IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

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IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION
MDL No. 2804
Case No. 17-md-2804
Judge Dan Aaron Polster

This document relates to:

County of Cuyahoga v. Purdue Pharma L.P., et al.
Case No. 17-OP-45004
City of Cleveland, Ohio v. Purdue Pharma L.P., et al.
Case No. 18-OP-45132
The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.
Case No. 1:18-OP-45909

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Volume 2
Continued videotaped deposition of
MARY APPLEGATE, M.D.

March 28, 2019
9:01 a.m.

Taken at:
Sheraton at Capitol Square
75 East State Street
Columbus, Ohio

Renee L. Pellegrino, RPR, CLR

APPEARANCES:
On behalf of Summit County and City of Akron:
Motley Rice
MICHAEL J. PENDELL, ESQ.
One Corporate Center
20 Church Street
17th Floor
Hartford, Connecticut 06103
(860) 218-2722
mpendell@motleyrice.com
On behalf of Cuyahoga County:
Napoli Shkolnik PLLC
CHRISTOPHER L. SCHNIEDERS, ESQ.
6731 W. 121st Street
Suite 201
Overland Park, Kansas 66209
(844) 230-7676
cschnieders@napoli.com

On behalf of Ohio Department of Medicaid:
Office of the Ohio Attorney General
MORGAN LINN, ESQ.
30 East Broad Street
26th Floor
Columbus, Ohio 43215
(800) 282-0515
morgan.linn@attorneygeneral.ohio.gov
- and -
Ohio Department of Medicaid
JULIE BABTIST, ESQ.
Lazarus Building
50 West Town Street
Suite 400
Columbus, Ohio 43215
(614) 752-5573
julie.babtist@medicaid.ohio.gov

On behalf of Cardinal Health:
Williams & Connolly
COLLEEN McNAMARA, ESQ.
725 12th Street, N.W.
Washington, D.C. 20005
(202) 434-5186
cmcnamara@wc.com

~ ~ ~ ~ ~

APPEARANCES, CONT'D:
On behalf of McKesson Corporation:
Covington & Burling LLP
RON DOVE, ESQ.
ANNA HAN, ESQ.
One CityCenter
850 Tenth Street, NW
Washington, D.C. 20001-4956
(202) 662-6000
rdove@cov.com
ahan@cov.com

On behalf of Walmart:
Jones Day
KRISTIN K. ZINSMASTER, ESQ.
90 South Seventh Street
Suite 4950
Minneapolis, Minnesota 55402
(612) 217-8800
kzinsmaster@jonesday.com

On behalf of Purdue Defendants:
Dechert LLP
DEBRA D. O'GORMAN, ESQ.
1095 Avenue of the Americas
New York, New York 10036-6797
(212) 698-3500
debra.ogorman@dechert.com

ALSO PRESENT: Jim Torok, Videographer

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THE VIDEOGRAPHER: We're on the record. Today's date is March 28, 2019. The time is approximately 9:01 a.m. We are here at the Sheraton in Columbus, Ohio to take the videotaped deposition of Dr. Mary Applegate in the case of National Prescription Opiate Litigation, Case Number 1:17-md-2804, to be heard in the United States District Court of Ohio by Judge Polster.

Counsel, please state your appearances for the record.

MR. DOVE: This is Ron Dove. I'm with the law firm of Covington & Burling on behalf of McKesson Corporation.

MS. HAN: Anna Han from Covington & Burling, also on behalf of McKesson.

MS. McNAMARA: Colleen McNamara from Williams & Connolly on behalf of Cardinal Health.

MS. ZINSMASTER: Kristin Zinsmaster of Jones Day on behalf of Walmart.

MS. O'GORMAN: Debra O'Gorman from Dechert on behalf of the Purdue Defendants.

MR. PENDELL: Mike Pendell, Motley Rice, for Plaintiffs.

MR. SCHNIEDERS: Chris Schnieders, Napoli Shkolnik, for Plaintiffs and Cuyahoga County.

MS. BABTIST: Julie Babtist, in-house legal counsel for Ohio Department of Medicaid.

MS. LINN: Morgan Linn, Assistant Attorney General for the Ohio Attorney General's Office, representing the Ohio Department of Medicaid.

MR. SCHNIEDERS: Mr. Dove, briefly, before we start, I just want to make a record of the fact that the Plaintiffs received a production last night at approximately 6:59 EST, which was hundreds of documents, something that we understand was in the possession of the defense as of Monday. We provided this to our vendor and then we had to work through to try to get a file to load and look at. We are proceeding with this deposition subject to the fact that we have not been able to completely review what was submitted last night and we'll be holding the deposition open based upon that and we'll possibly have to come back and do this again.

MR. DOVE: And just so the record is clear, we did receive a -- we received a number of productions since the date of Dr. Applegate's last deposition, all of which have been timely posted on the RICO site. We received our latest production from Ohio Medicaid on Monday. There were some issues with regard to confidentiality designations, such that were confirmed, I guess, at 10:30 yesterday from the Ohio Department of Medicaid. As soon as those confidentiality designations were confirmed, we immediately had our vendor post those documents on the RICO site, as is the practice in these cases. We also, as a courtesy to counsel for the Plaintiffs, provided, on their request, a zip file as quickly as we could to do that, and -- but we understand your desire to potentially keep the deposition open.

We also, in conversations with Ohio Medicaid, note that there are some additional documents still yet to be produced, e-mails and some other documents, and that we are also, you know, leaving the possibility of the deposition being kept open if we're unable to resolve any outstanding issues by other means.

MR. SCHNIEDERS: And, lastly, I just want to make clear that Plaintiffs were not aware of this production, again, until eastern last night, so it sounds like at least as of 10:30 yesterday morning, you knew that there were confidentiality issues and that they could be at least addressed with us, and the production happened on Monday.

Subject to all those objections, we'll go ahead and move forward and deal with it later.

MARY APPLEGATE, M.D., of lawful age, called for examination, as provided by the Federal Rules of Civil Procedure, being by me first duly sworn, as hereinafter certified, deposed and said as follows:

CONTINUED EXAMINATION OF MARY APPLEGATE, M.D.

BY MR. DOVE:

Q. Good morning, Dr. Applegate.

A. Good morning.

Q. As I said, my name is Ron Dove, and I'm with the law firm of Covington & Burling, and we first met when we began your deposition back on January 23rd, and I represent McKesson Corporation in this litigation. McKesson is one

of the Defendants.

Do you understand, Dr. Applegate, that this is a continuation of your January 23rd deposition?

A. Yes, I do.

Q. And that you're testifying both on behalf of the Ohio Department of Medicaid as a 30(b)(6) witness and in your personal capacity as before?

A. Yes.

Q. Is there any reason why you cannot give complete and truthful testimony today?

A. No.

Q. And are there any medications you are taking or any illness or condition that would make it difficult for you to give complete and truthful information?

A. No.

Q. What did you do to prepare for today's deposition session beyond what you did to prepare for the last session on January 23rd, if anything?

A. Earlier this week I met with the Department of Medicaid and the Attorney General' and they informed me that they had a number of

documents that were submitted. I did not review all of them. The discussion was --

MS. LINN: I wouldn't get into the specifics of our discussion because it's privileged.

A. So I just didn't read every single document. I'm just aware that there were documents that were submitted.

Q. So you had -- you met with your -- you met with attorneys from the Ohio Department -- the AG's office and the Ohio Department of Medicaid, and that would be Ms. Linn and Ms. Babtist?

A. That's correct.

Q. Did you meet with anyone else?

A. No.

Q. Did you review your prior deposition transcript?

A. Proximate to the deposition I did, but not in the recent week.

Q. Did you -- other than the documents that you mentioned and your deposition transcript, did you review any additional information?

A. No.

Q. Did you speak with anyone on the pharmacy team regarding any of the outstanding issues from last deposition?

A. There were a couple of points of clarification that I believe you asked.

Q. Yes. And did you speak with your pharmacy team with regard to those?

A. Yes.

Q. Did you do anything else in preparation for today's deposition?

A. I did review just one of the presentations that was a summary of the work over the last several years, which was discussed at the last deposition.

Q. Dr. Applegate, has anything changed in your role or your responsibilities at ODM since your deposition on January 23rd?

A. I think I'm aware of additional work that needs to be done, but other than that, no.

Q. We understand that a new Ohio Department of Medicaid director, Maureen Corcoran, was appointed in January 2019, correct?

A. That is correct.

Q. Has Director Corcoran made any

policy changes related to opioids or opioid coverage?

A. No.

Q. Are there any changes that the director expects to make this year that you're aware of with regard to opioids or opioid coverage?

A. Not that I'm aware.

Q. During the last deposition on January 23rd, you testified that the prescription drug benefit was carved into managed care, then carved out, and then back into managed care, correct?

A. That is correct.

Q. When was the prescription benefit first carved into managed care?

A. I would have to check with people from the agency.

Q. Do you have a general idea of when it was?

A. Early 2000s. I really would need to have someone who was here at that time let me know.

Q. When you arrived at the Medicaid agency in 2006, was the -- was the prescription

benefit carved into managed care at that time?
A. I don't recall.
Q. Is it correct that between February 1st, 2010 and October 1st, 2011 the prescription drug benefit was carved out of managed care?
A. There was a year. I would have to double-check exactly which year that was.
Q. But if I represented to you that between February 1st, 2010 and October 1st, 2011 the prescription drug benefit was carved out of managed care, that would not surprise you?
A. That's correct.
Q. Other than that one-year time period, and I understand you don't remember the exact date but that one-year time period, was there any other periods that you're aware of where there was a prescription carve-out?
A. When the agency was largely fee for service, the drug benefit was also fee for service.
Q. And when was that?
A. Again, I would have to check with folks who were in the agency at that time.
Q. But that would have been before 2006?

A. Yes.
Q. I believe you also testified previously that there was a requirement that the fee-for-service preferred drug list and the managed care plans preferred drug lists should have an 80 or 85 percent agreement.
Do you recall that?
A. Yes.
Q. Do you know what time period that requirement of 80 or 85 percent agreement between the preferred drug lists was in place?
A. I would need to check. I should perhaps just remind you that I was -- the agency became a stand-alone agency in 2013 and so my knowledge of the pharmacy program essentially starts in some detail at that time. When I first went to the agency, I was there part time and mainly worked on prior authorization and was not directly connected to the pharmacy part of the program.
Q. Is it your understanding that the 80 or 85 percent agreement requirement was in place prior to 2013 or after 2013 or both?
A. I suspect it's both.
Q. What are the current obligations of

managed care plans to cover drugs that are on the fee-for-service preferred drug list?

A. They are required not to cover less than what's on the fee-for-service list; however, they are free to offer a broader benefit.

Q. And how long has that requirement been in place, to the best of your knowledge?

A. Since its inception.

Q. Since what's inception?

A. Since managed care came to be in the program.

Q. So just so I understand, and I'll have more questions about this, so if a drug is on the fee-for-service preferred drug list, it also needs to be on the managed care preferred drug list?

A. So it must be covered. Whether or not there's a prior authorization is a separate question. It must be on the formulary, and then the formulary is different from what's on the preferred drug list.

Q. Just drilling down a bit, my understanding from your testimony last time is that the formulary covered by fee for service is

pretty broad. I mean, it's every drug that is part of the federal Medicaid rebate program, correct?

A. Not exactly. So what's on the formulary is everything that's FDA approved for those specific indications. The rebate program is part of what determines what's on the preferred drug list. That may or may not correlate with the need for a prior authorization.

Q. And so what you're saying, and again we'll get into this in more detail, is that it's possible for the preferred drug lists of different managed care plans and fee for service to differ between each other, correct?

A. That's correct. And connected to your prior question about that 80, 85 percent, that's actually what that means, so that variation is not to exceed that 80 or 85 percent threshold.

Q. And maybe this also relates to the 80 to 85 percent issue, but how much discretion do Medicaid managed care plans have to determine the status of drugs on their preferred drug lists compared to those on the fee-for-service

preferred drug lists? By status I mean, you know, prior authorization, step therapy, quantity limits, that sort of thing. How much discretion do Medicaid managed care plans have to make those determinations on their preferred drug list compared to fee-for-service preferred drug lists?

MR. SCHNIEDERS: Are you talking about Ohio or are you talking just generally across the country?

MR. DOVE: This is all Ohio unless I specify otherwise, but Ohio.

A. The discretion they have to vary is within that threshold of 80 to 85 percent, so approximately 20 percent. If prior authorization is required, every plan has their own processes that include their own P&T and they can decide what they want the criteria to be for their prior authorization, for example.

Q. When you say every plan has its own criteria, can you elaborate a little bit more for me? What do you mean by criteria in that context?

A. So let's say as part of, you know, falling within that 80 percent threshold, they

agree that they're going to cover drug A. The first plan may say you have to have the diagnosis and you have to have failed one prior drug. The second plan may say -- they might allow a broader range of diagnosis, but you have to have failed two drugs before you actually can receive the drug that's requested. So there may be age restrictions. They may add additional detail related to requirements under the FDA approval.

Q. And so there could be considerable variability both between plans and -- between different managed care plans and also as compared to managed care plans to the fee-for-service plan; is that right?

A. Yes.

Q. And the 80 to 85 percent threshold, where could we find information about that? Where would that be located?

A. I'm not sure. I'd have to ask my pharmacy team.

Q. Do you know if it's published somewhere even? If you don't know where it is, do you know that's a publicly available threshold?

A. My understanding is that was part of the operations, so not necessarily a public-facing document. It was part of how we did business.

MR. DOVE: We would ask the agency to look for documents relating to the 80 to 85 percent threshold number.

Q. Can Medicaid managed care plans decide to require prior authorization or step therapy for a drug if the fee-for-service preferred drug list does not?

A. Yes.

Q. Can a Medicaid managed care plan decide not to require a prior authorization or step therapy if the fee-for-service plan does?

A. Yes.

Q. Can Medicaid managed care plans impose quantity limits on drugs that do not require prior authorization or step therapy on the fee-for-service preferred drug list?

A. Yes.

Q. And then how about vice versa; can Medicaid managed care plans decide not to impose quantity limits on drugs for which the fee-for-service preferred drug list requires

prior authorization or step therapy?

A. Yes. We do not dictate the exact edits within the pharmacy program. We ask that they adhere to all state laws. And there may be flexibility in how their systems are set up as to how they actually get there.

Q. And just to tie the loop on this line of questioning, can Medicaid managed care plans impose quantity limits on drugs that do not have quantity limits on the fee-for-service preferred drug list?

A. Yes.

Q. And can Medicaid managed care plans decide not to impose quantity limits on drugs that do have quantity limits on fee for service?

A. Yes.

Q. During our session in January you mentioned that medical directors from the managed care plans follow certain standards of safety when considering the drug coverage that is offered?

A. Yes.

Q. Could you tell us a little bit more about, you know, who are these medical directors? Who were you talking about when you

used that term?

A. Every managed care plan is required to have a medical director to oversee all the clinical activities within their program, and we meet with them routinely to review issues, discuss population health, and discuss any issues of safety that might be relevant.

Q. And do you know what the requirements are to be a medical director? I mean, what types of individuals typically serve in that role for managed care plans?

A. There's a wide variety, but they all must be board certified and have expertise in the care of patients over a broad span, so everywhere from, you know, birth to death and every single condition, and if all of those requirements cannot be met with one individual, many of the plans have several medical directors to be sure there's adequate expertise in behavioral health, physical health and all sites of service.

Q. How do the medical directors make their determinations about which drugs to cover?

A. Each of the managed care plans have their own internal processes that largely are

similar to what we have in fee for service, so they all have a P&T committee, they all have a DUR, a drug utilization review board, and those similar processes.

Q. And when you talked about standards of safety, what -- was that just a general term? What standards of safety are applied in making these determinations?

A. These are clinical standards that may be considered best practice in clinical care. So, for example, if someone is on a ventilator, we don't just take them off without testing that their lungs are ready, that they're strong, that they're not on medications that would interfere with spontaneous respirations, so that would be an example of a clinical standard of safety.

Q. And are there standards of safety that relate specifically to opioids that you're aware of?

A. Yes, there are.

Q. And what standards of safety would be considered in that context?

A. They do write books about this, so I likely will not review all of them, but the

combinations of drugs that are prescribed, how fast someone is taken off medications, how we might start medication-assisted treatment, start and wean somebody from medication-assisted treatment or other controlled substances. These are all considerations that are relevant to safety.

Q. And these are all standards of safety that the medical directors of the managed care plans are supposed to be familiar with, correct?

A. Correct.

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(Thereupon, Applegate Deposition Exhibit 21, The Ohio Department of Medicaid Ohio Medical Assistance Provider Agreement for Managed Care Plan, Revised 2/2019, was marked for purposes of identification.)

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Q. I'd like to mark now as Exhibit 21 a document entitled "The Ohio Department of Medicaid, Ohio Medical Assistance Provider Agreement for Managed Care Plan." I ask for you to take a moment to look at that.

MR. SCHNIEDERS: And just to be clear, counsel, this is an excerpt. It looks like there was 216 pages in the actual document.

MR. DOVE: I'll get to that in a moment.

Q. So this is -- first of all, do you know what this document is reviewing it, Dr. Applegate?

A. Yes. This document spells out the requirements for the managed care plans as it relates to participating in our program.

Q. And I can -- following up with Plaintiffs' counsel, I can represent that what we did with this, we pulled this off of Ohio Medicaid's website and this is only the main contract. It does not include the appendices.

A. Okay.

Q. If I could direct your attention to the fourth paragraph on the first page. The third line down, it states that "The MCP," which I assume means managed care plan, "has provided and will continue to provide proof of the MCP's capability to provide quality services efficiently, effectively and economically during the term of this agreement."

Do you see that?

A. Yes.

Q. And let me step back for a moment. So I take it, is this the model contract that managed care plans are -- are supposed to enter into? What is the purpose of this document?

A. It specifies the terms and conditions and requirements for the managed care plans to take care of members, the beneficiaries in the Medicaid program.

Q. So going back then to that fourth paragraph, the portion that I just read, is prescription drug coverage considered one of the "quality services" contemplated by this agreement?

MR. SCHNIEDERS: Are you talking about this agreement that's dated the end of February of 2019 or are you talking about a different agreement? I just want to make sure we're clear on the timing of this document.

MR. DOVE: I'm talking about this document, which appears to have been revised in February 2019, but if -- we printed it off the website, so I can ask it both ways, but -- well, I will ask it both ways just to make it clear.

Q. As of today, is prescription drug coverage considered one of the "quality services" contemplated by this agreement?

A. The pharmacy benefit is part of the agreement with the managed care plans, yes.

Q. And that's the pharmacy benefit that is considered one of the quality services contemplated by this agreement?

A. Well, let me clarify. I'm not sure exactly what question you're asking. The program does cover goods as well as services. This term is used as a holistic way to take care of patients, and so in that broader context, yes.

Q. And that would have been true not just today but true for as long as you had relationships with managed care plans that you're aware of?

A. Yes.

Q. Is this agreement with managed care plans a tool that ODM can use to effect prescription drug coverage by its managed care plans?

A. Yes.

Q. And how can it do that?

A. We can set forth requirements related to how some of the services are either provided or monitored.

Q. Can you give me an example or two of that in the, sort of, pharmacy benefit context?

A. We can require that there are routine meetings with the directors of all the pharmacies to review utilization concerns if there are issues. Specifically in this case, related to the opioid epidemic, we met with them to be sure that they were monitoring utilization and that they all put edits in place to adhere to state guidelines.

Q. Does the Medicaid agency impose any restrictions on how managed care plans can structure their preferred drug lists?

A. As you mentioned earlier, they are required to provide not less than what is provided in fee for service. As I also mentioned earlier, we do have standards of safety, so if there are sudden changes that impact more than one percent of their population, they must give us notification in advance. That might be a good example.

Q. And where can one find a listing of

these restrictions?

A. I would have to ask my pharmacy team.

Q. And maybe you touched on this earlier. I just want to make sure I'm clear with it. Has the Medicaid agency ever, in the time that you've worked there, imposed restrictions on how its managed care plans structure their preferred drug lists?

MR. SCHNIEDERS: Are you asking this in her personal capacity or in her 30(b)(6) capacity?

MR. DOVE: In her 30(b)(6) capacity.

MR. SCHNIEDERS: I'll object to the extent it goes beyond the time she's been there, but go ahead.

MS. LINN: You can answer that.

A. We referenced this earlier related to the consensus list, that 80 percent that we talked about, so they would consider that to be a restriction.

Q. Other than that consensus list, are there any other restrictions that the Medicaid agency has imposed on its managed care plans and how they structure their preferred drug lists?

A. If there were issues of safety, we actually did ask that they follow procedures to ensure that members were safe. So, for example, on a certain date they are not allowed to suddenly switch all of their members from one controlled substance, for example, to an entire other one if, in fact, there could be differences by availability, if, in fact, those butted up against the state requirements to access to specialists beyond certain thresholds. So that may be an example of how we've done that in the past.

Q. And have these safety issues that you're discussing ever come up within the context of opioids that you're aware of?

A. They have come up as it relates to medication-assisted treatment, so yes.

Q. And could you explain a little bit more how that worked within the context of Medicaid -- or MAT?

A. Okay, medication-assisted treatment.

Q. Yes.

A. Okay. So one of the managed care plans on one occasion wanted to switch brands, and we required that -- which is allowed, of

course. This is a common practice among managed care plans. However, we required a very detailed analysis of the dosages that patients were on and the availability of clinicians who could help navigate that change in brand, because particularly for that problem, it could create instability in the recovery of patients. So we did require a much longer runway and communication with the providers as well as with the members before they took such an action.

Q. And how did this issue come to ODM's attention?

A. We received the announcement that as of a certain date, all of their members were required to switch.

Q. Other than this one instance with regard to medication-assisted treatment, is there -- do you recall any other instance where issues of safety caused the Medicaid agency to impose a particular restriction on one of its managed care plans' preferred drug lists?

A. I would have to check with the detail of my pharmacy team since I'm not the one who's closest to all of the detail.

Q. But sitting here today, you don't

recall any other instance, correct?

A. That's correct. There could have been smaller ones, but again, I'd have to defer to my pharmacy team.

Q. Does the Medicaid agency impose any restrictions on how many drugs the managed care plan may include on their preferred drug lists, you know, compared to the overall formulary, sort of a percentage or any other sort of restriction like that?

A. No.

Q. Does the Medicaid agency require managed care plans to list a specific number of drugs within a category on its preferred drug lists?

A. No.

Q. Does the Medicaid agency require managed care plans to have a specific number of drugs within a category, such as the opioids category -- does the agency require managed care plans to have a specific number of drugs within a category that are preferred and do not require prior authorization?

A. That's that consensus list that we talked about, and as I mentioned earlier, they

must make available what we have in fee for service, but they have the flexibility to cover more.

Q. Dr. Applegate, do the actual agreements with the managed -- that the agency has with the managed care plans, do those agreements differ from the sample agreement that we just looked at?

A. I can't speak to that. All of the managed care plans have the same provider agreement, but I certainly haven't gone through every page of all of this to actually verify that independently.

Q. But that's helpful. Each of the managed care plans have the same agreement with ODM?

A. That's correct.

Q. Are there other tools besides the agreement that ODM -- strike that.

Besides the agreement that we just looked at as Exhibit 21, are there any tools that the Medicaid agency can use to effect prescription drug coverage by its managed care plans?

A. Yes. The provider agreement does

not get into all of the detail of the very specific population health improvement initiatives, so they're referenced generally, and that gives us the flexibility over the period of the contract to be nimble in addressing certain needs. So, for example, we have special programs in place for pregnant women who have opioid use disorder, we have special programs for recently incarcerated individuals specifically to address outcomes -- access, number one, and then quality and outcomes for specific populations.

Q. And those specific programs that you just mentioned apply not just to fee for service but to the managed care plans as well?

A. That's correct.

Q. And has that tool been available to the Medicaid agency for as long as the agency has been involved with managed care?

A. I can only speak to the time that I was there.

Q. During the time that you've been there.

A. So that has been true since I've been there.

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(Thereupon, Applegate Deposition Exhibit 22, E-Mail from Benjamin Link to Several Recipients, dated December 19, 2018, with Attachments, was marked for purposes of identification.)

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Q. Dr. Applegate, I'd like to hand you a document that has been marked as Exhibit 22, and I'll represent to you that this document -- I'll represent to you that this document was produced by the -- by ODM in this litigation. It appears that our exhibit copy, that the Bates label was cut off in the copying process, so I will read it for the record. This can be found at ODM_040493 through 04049 -- or, excuse me, through 040500.

Do you recognize this document, Dr. Applegate?

A. No. I do recognize the content of it, so I'm not personally responsible for the in-pharmacy processes because the pharmacy team is.

Q. Can you describe what this document

is, to the best of your understanding?

A. This looks like an accounting of different classes of drugs with a consensus rate by class.

Q. And there's a reference here to Change Healthcare. Is that ODM's pharmacy benefits administrator?

A. Yes, it is.

Q. And ODM has had or the Medicaid agency has had past pharmacy vendors, correct, prior to Change Healthcare?

A. That's correct.

Q. And those have included Gould, Xerox and ACS, correct?

A. That's correct.

Q. And they propose or they process pharmacy claims for the Medicaid agency, correct?

A. That's correct.

Q. Can you describe what types of decisions -- strike that.

Can you describe what types of coverage decisions are made by pharmacy vendors with regard to opioids, if any?

A. The pharmacy vendor does not make

the coverage decision; the agency makes the coverage decision, and they actually pay the claims for us.

Q. So their role is more of an administrative one, not a policy-making or sort of medical decision-making role?

A. That's correct.

Q. How long has Change Healthcare been providing these consensus reports to the Medicaid agency?

A. I would have to check with my pharmacy team. This vendor has not been with the agency terribly long.

Q. Would this type of document cross your desk, Dr. Applegate?

A. Usually not.

Q. Do you know whether previous pharmacy benefits administrators, the ones we just talked about, Gould, Xerox, ACS, whether they provided similar reports to the Medicaid agency?

A. I would expect that they would, although I can't comment because I haven't seen them.

Q. If you could turn to page 3 of this

report, and by that I mean the -- what's numbered page 3, and in particular, to the second bullet point or second -- excuse me, the second to last bullet point states that "Change Healthcare delivers to ODM a summary report identifying percentage of consensus among plans and FFS at the NDC and GPI 10 level."

Do you see that?

A. Yes.

Q. Is this the summary report that's being described in this document?

A. I actually don't totally know because this is at such a high level, but the tops of the graph do suggest GP 110 and NDC.

Q. What does GP 110 mean?

A. It's a class of drugs, but again, I'd have to -- I'd actually have to check with my pharmacy team. The NDCs are the very specific numbers of each particular -- every drug has an NDC number.

Q. So, you know, by looking at these tables in this exhibit, I mean, can someone tell what the consensus is among the managed care plans and the fee-for-service plan with respect to drugs requiring prior authorization?

A. What this articulates is a consensus rate the way Change Health has calculated it with their methodology, so I'm not sure actually how that compares to what was done with prior PBAs, and then I'm also -- there's not a huge amount of detail related to specialty drugs, physician-administered drugs. You know, there are many categories of drugs. So with just this summary statement -- I'm sure the pharmacy team actually understands the detailed methodology, so I would actually have to defer to them because this is just a very, very high level calculation.

Q. So do these -- do you have an understanding of whether these consensus rate percentages that are included in this document, in figure 1 the consensus rate of 54.3 percent, and in figure 2 the consensus rate of 67.76 percent, and in figure 3 the consensus rate of 72.45 percent -- do these percentages relate in any way to the 80 to 85 percent consensus number that we were discussing earlier or is this a different type of analysis?

A. So I believe it's related. Whether or not it's the same methodology, I cannot

comment on. So as you note, when they use one methodology, they get one number, and when they use another methodology, they get another number. It could be that in prior years they refined their methodology. So, again, I would have to check with my pharmacy team, but yes, I think they're related.

Q. I believe we talked earlier about how one managed care plan can require some kind of prior authorization for a particular prescription opioid while another managed care plan might not require prior authorization for that opioid, correct?

A. Correct.

Q. And the Medicaid agency allows that, correct?

A. Correct.

Q. Why does the Medicaid agency allow that to occur?

A. Well, the plans are able to be more flexible than we can be. They may not want to make as many changes as another plan. They may have business operations that they're trying to honor. So we don't actually, you know -- we actually pay them to do the best job they can to

actually manage the health of patients without taking away all of their flexibilities.

There are new drugs that come on and off the program, mainly on, so as you add new drugs, you can imagine that the consensus rate actually might go down until you get your processes together, so some flexibility actually is required to respond to the changes in the field.

Q. But if the Medicaid agency wanted to, it could control this, right; it could say, look, all managed care plans must require a prior authorization for a particular opioid, correct?

A. So the state does have flexibility; however, the perspective of the agency is that if a plan wants to do a particular effort, for example, around removing barriers for patients with diabetes, they actually can look at their pharmacy benefit and try to create a path of easier access for better diabetes control, for example. And so that may impact how they structure the pharmacy benefit.

Q. Let's kind of stay with opioids for a moment, though. Again, the agency, if it

wanted to, could require prior authorization across all its managed care plans for particular opioids, correct? I understand it chooses not to, but it could do that if it wanted to.

MR. SCHNIEDERS: Object to the form. It's also been asked and answered.

Go ahead.

A. Yes. We could have essentially the fee-for-service formulary. Yes, that is possible.

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(Thereupon, Applegate Deposition Exhibit 23, Molina Healthcare of Ohio Preferred Drug List (Formulary), was marked for purposes of identification.)

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Q. Dr. Applegate, I'm now handing you what we've marked as Exhibit 23. This is the current Ohio preferred drug list for Molina, which I understand is one of the five Ohio Medicaid managed care plans, and we printed this off Molina's public website. And I'd ask you to turn to pages 6 and 7 of this document and then just leave it in front of you. We're going to

show you another document and then ask questions.

And what I'm handing you now is what was previously marked in your January deposition as Exhibit 6, which is a copy of the 2018 Ohio Medicaid fee-for-service preferred drug list that we discussed at that deposition.

And in this document I'd like you to turn to page 9 of Exhibit 6, and you'll see there that several drugs -- well, if you could turn to page 9 and then I'll ask you a question. All right. Again, turn to page 9 of the fee-for-service preferred drug list, Exhibit 6. You'll see that several drugs listed on the long-acting opioids -- long-acting oral chart, including hydrocodone in the second white row, and methadone in the last white row, are not on the Molina preferred drug list. I ask you if you see that.

A. I'm not sure -- what you're asking me to do is compare these side by side?

Q. Yes. Just compare them and confirm for me that the -- that hydrocodone, which is in the second white row of the -- on page 9 of Exhibit 6, and methadone, which is in the last

white row, neither of those drugs are included on the Molina preferred drug list.

A. That's correct.

Q. And on the next page, page 10, of Exhibit 6, if you could confirm that oxymorphone is in the prior authorization required column in the fee-for-service preferred drug list but on the Molina list it does not have prior authorization next to it.

Do you see that?

A. Yes.

Q. And I was going to ask you more questions about this, but given your prior testimony, my understanding is -- tell me if I'm right or wrong -- is that that doesn't surprise you because there's a great deal of variability between the fee-for-service list and the managed care lists, correct?

A. Yes, within that consensus process that we discussed.

Q. If you could turn to page 6 of the Molina healthcare preferred drug list, which is Exhibit 23, right under the subheading "Opioid Analgesics" at the bottom -- do you see that?

A. Yes.

Q. -- it states that, "All opioid analgesics are subject to Ohio Department of Medicaid opioid policy."

Do you see that?

A. Yes.

Q. What is the Ohio Department of Medicaid opioid policy?

A. You recall I talked about the pharmacy directors having routine meetings, and they worked through the detail of the kinds of limits and edits that are required to meet state guidelines. Many of these guidelines, as we mentioned last time, relate to, for example, quantity limits for acute pain for new patients, as well as other checkpoints as delineated by the guidelines.

Q. Does the Medicaid agency maintain documents describing the Ohio Department of Medicaid opioid policy?

A. I would have to ask my pharmacy team details about documentation of those internal operational processes; otherwise, we actually look to published state guidelines for the policies.

Q. And does the Medicaid agency require

all managed care plans to adhere to its opioid policy?

A. Yes.

Q. And when did this opioid policy go into effect, if you know?

A. I actually don't know specifically, and, again, let me clarify that the policy that you speak about is actually state law, so I wouldn't say that Medicaid is the only entity that actually owns it. This is actually how we operationalize state law.

Q. And have you been involved personally as medical director in the operationalizing of state law in this way?

A. We have an entire team that actually assists in various capacities.

Q. And who is on that team?

A. There are members from almost all areas of the department. The last time we talked a bit about the governor's cabinet opiate action team. So we have people in managed care who are part of the lock-in program. We certainly have our pharmacy team, our managed care team, the people involved in special efforts around special populations, as I

referenced, the recently incarcerated pregnant women, infants. So it's a team.

Q. What requirements does the opioid policy impose on managed care plans opioid coverage?

A. I'm not sure what you're asking. You want me to repeat all of the guidelines?

Q. No.

A. Okay. So that's the basis of all of our policy.

Q. I mean, we've talked about some examples. For example, does the Medicaid agency require managed care plans to require prior authorization for all long-acting opioids?

A. We require that long-acting opioids are not utilized for acute pain, which is what's in the guideline. Exactly how the managed care plan does that, they have flexibility around doing that. They can actually work with hospitals, they can work with providers, they can work at the point of sale with pharmacies, and they can work with the pharmacy edits inside their pharmacy systems. So they have many ways that they can actually implement.

Q. I believe you previously testified

that all managed care plans provide their formularies and preferred drug lists to the Medicaid agency. Does that --

A. Yes.

Q. And they've done that since 2006, correct?

A. I can't comment on before I was there, but I would expect that to be true.

Q. You were there since 2006, correct?

A. Yes, but not involved -- you know, I really did prior authorization very specific clinical tasks until I was there full time.

Q. Which was 2010 roughly?

A. At the end, yes, '11.

Q. But in any event, it's your understanding and expectation that the managed care plans working with the Department of Medicaid would provide them with copies of their formularies and preferred drug lists, correct?

MR. PENDELL: Object to the form.

A. Yes.

Q. Who at the Medicaid agency is responsible for maintaining those formularies and preferred drug lists?

A. That should have been overseen and

managed by the lead pharmacist and the pharmacy team.

Q. So that would have been Margaret Scott in the early days, correct?

A. Yes, with her team.

Q. And Dr. Wharton today, correct?

A. Yes, that's correct. Yes.

Q. Now, the Medicaid agency has access to its own claims data that's kept in the Medicaid information technology system or MITS, correct?

A. Correct.

Q. And I think you previously testified that ODM has access to the State Board of Pharmacy's Ohio Automated Rx Reporting System, or O-A-R-R-S, correct?

A. We have constrained access to the OARRS reporting system. We have a very tight partnership with the Board of Pharmacy, in which aggregate information is shared.

Q. Let me drill down into that a little bit. Aren't you able to access the OARRS database to look up particular patients or prescribers or pharmacists of concern?

MR. PENDELL: Objection to form.

MS. LINN: You can answer the question.

A. We are able to look up one patient at a time, particularly if we have concern, but we actually cannot explore the database independently. There are special laws that actually govern access to that database.

Q. So on one hand, you can do one patient at a time, but then you mentioned aggregate data. Can you explain what that means?

A. Yes.

We have a tight partnership with the Board of Pharmacy. Under the umbrella of our past governor's cabinet opiate action team -- GCOAT we called it for short last time. And as part of that, all of the agencies in the state were interested in the effect of the prescribing guidelines and the impact of prescription drugs on the opioid-related death rate. So that's actually really what drove the formation of that group.

So as part of that, we received regular reports from the Board of Pharmacy related to who was checking OARRS, which sort of

drugs were being prescribed, what the proportion of short acting and long acting were at varying morphine equivalent doses to really get a handle of what was going on with prescription opioids.

Q. And did the Medicaid agency have input into the items that are included in that Board of Pharmacy report?

A. We helped them develop the methodology, essentially to develop the measures that were then reported and tracked over time.

Q. And so under this agreement with the Board of Pharmacy, if the Medicaid agency wanted to do other analyses that it thought would be helpful to its -- to the performance of its duties that involved the OARRS database, could it conduct those analyses with the Board of Pharmacy?

A. Not easily. We have to go through an entire legal process with a DUA and a series of -- data utilization agreement, and a series of other legal agreements with very -- a very specified purpose. So that has not been an easy path and we do not have a body of research related to the Medicaid-only portion of the OARRS database.

Q. You say it's not easily but it would be possible, correct, if you could get agreement with the Board of Pharmacy under this relationship you have with them; is that fair?

A. It's fair, but let me tell you, we've been waiting four years for a single research project, so, in reality, I actually do not think that that's a feasible activity under the current rules that we have right now.

Q. And you mentioned one report, I believe -- maybe it was a series of reports, but I know you mentioned one report from the Board of Pharmacy. Does the Medicaid agency receive, you know, regular reports from the Board of Pharmacy that discuss drug utilization or prescription opioids?

A. Under that GCOAT group, we received at least quarterly reports related to utilization, just as we received quarterly reports from the Department of Public Safety related to seizures and that sort of thing. The Board of Pharmacy does publish an annual OARRS report, and that's actually a source of information as well.

Q. And has the Board of Pharmacy been

providing these sorts of reports since the time you've been at -- for the full time you've been at the agency?

A. As I mentioned earlier, we helped them develop the methodology, so I don't think they existed right when I came to the agency but they were developed over the course of that time.

Q. And when did you develop that methodology?

A. So there's several measures, so it's actually probably over a period of a couple years. I'd have to ask my colleagues at the Board of Pharmacy for the exact dates.

Q. Do you have a general understanding of the time frame that this occurred?

A. I actually would have to ask them. The point at which it was official I'm actually not clear because it was a process. We certainly had the first measure of total solid doses dispensed, you know, at least approximately 2012, but over time we have a much more robust series of measures that we've tracked, including utilization, doctor shopping, the number of patients over 80 morphine

equivalents for more than three months, et cetera. So the annual report really is quite complete and does reflect the number of measures that were developed.

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(Thereupon, Applegate Deposition Exhibit 24, A Drug Utilization Review of Duplicative Long-Acting Opiate Use, September 2012, Beginning Bates Number ODM_039326, was marked for purposes of identification.)

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Q. Dr. Applegate, I would like to hand you now a document that was produced by ODM in this litigation. It bears the Bates label ODM_039326 through 039327. It's entitled "A Drug Utilization Review of Duplicative Long-Acting Opiate Use September 2012." I just ask you to look at that document and tell me if you recognize it.

A. No, but I can look at it now.

Q. Sure. You can take a moment just to review it and then provide your understanding what this document is.

MS. BABTIST: This computer is looking like it's trying to restart.

THE VIDEOGRAPHER: Let's go off the record.

Off the record.

(Recess had.)

THE VIDEOGRAPHER: We're back on the record. The time is 10:29.

Q. Dr. Applegate, if we could just turn back again to Exhibit 24, and if you could tell me what that document is to the best of your understanding.

A. This is a drug utilization review of what they're calling duplicative long-acting opiate use dated September 2012. It begins with the objectives of the evaluation that summarize the clinical best practice of not being on two long-acting different opioid products at the same time. And the second point is that there's an intervention in which the DUR committee identifies patients who may be on duplicative long-acting opioids and they send letters of educational information and guidance for checking the OARRS system, which is the prescription drug monitoring program system,

which tells the clinicians the entirety of the controlled substances that were prescribed for that patient. In here is the suggestion that one prescriber may not know what another prescriber has for that same patient and that they'll be reevaluating this.

Q. And do you know why this document was prepared?

A. I don't have the rest of the context, but the suggestion is that they're aware that there are circumstances that they can see based on pharmacy claims in which best practice is not being followed, but there's no additional context or reasons for it or conclusions or anything like that. It does appear that there are additional pages since this stops mid-sentence.

Q. Dr. Applegate, you can put that document aside.

I'd like to now show you what's been -- we're marking as Exhibit 25. It bears the Bates numbers ODM_040711 through 040756. And I'll represent to you that this was produced by the Medicaid agency in this litigation.

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(Thereupon, Applegate Deposition Exhibit 25, Ohio Department of Medicaid (ODM) Quarterly Clinical Report Q2 2018, Beginning Bates Number ODM_040711, was marked for purposes of identification.)

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Q. If you can take a look at that document and tell me if you recognize what it is.

A. This is a quarterly clinical report from the second quarter of 2018 produced by Change Healthcare.

Q. And how long has Change Healthcare been providing these clinical reports to the Medicaid agency?

A. It is part of their requirement since they became our pharmacy benefit administrator.

Q. And does ODM receive any other drug utilization information from Change Healthcare?

A. I believe this is just the clinical report. I think there are reports related to claims paid, expenses. Yes, there are additional reports.

Q. And did the Medicaid agency receive such information in the past from Change Healthcare's predecessors, like Gould and Xerox?

A. I cannot comment on the entirety of what the reports in the past were. I do know that since we've had Change Health -- Healthcare, we wanted to have a clinical focus because the shift is to not just pay claims but actually to take better care of people. So to that end, it's possible that the clinical nature of this report is something that's happened in more recent years.

Q. If you could turn your attention to the executive summary page, which is ODM_040715. And I'd like to direct your attention to the third paragraph, last sentence, where it talks about "efforts to coordinate drug coverage across the ODM program such as through the single preferred drug list initiative."

Do you see that?

A. Oh, yes.

Q. What is the single preferred drug list initiative?

A. As part of our effort to take care of populations better, one of the complaints

that we heard from clinicians is that there was too much variation in -- in the types of medications that they needed for adherence, for best adherence, so one of the policy thoughts at that time was that we would take classes of medications and require that all of the plans treat them the same. And we were looking at the -- a couple of different areas that were of high impact for the agency. So opioid use disorder and diabetes are of particular interest in that regard.

Q. And what was the result of that effort?

A. So that never went through. The managed care plans objected to the idea. So we're trying to find different ways to meet the same objective.

Q. But if it were up to Ohio Medicaid, this single preferred drug list initiative would be in place? Is that the preference of Ohio Medicaid?

A. I'm not sure I can speak for the entire agency since we do have a director who works in conjunction with her other partners in state government, but from a clinical

perspective, reducing variation in adherence to chronic medications is a sound strategy.

Q. Just directing your attention further on in the report to page ODM_040744, there's a reference to opioid dashboard reports. I'd just like you to explain, what are -- just in a general way, what are the opioid dashboard reports.

A. Well, what we wanted to do was to have our finger on the pulse of prescription opioids because, you know, years ago we were aware that about a quarter of the opioid-related deaths had some sort of prior prescription opioid, and many of the collective actions across the agencies were all about safe prescribing and not starting that journey of addiction through prescription medications. So to that end, you know, related to my comments with the Board of Pharmacy and the protection of the OARRS information, we at least internally wanted to monitor progress because we had a number of efforts in play, including the pharmacy edits and our work with the managed care plans and the coordinated services program, the lock-in to pharmacies, for example, so we

wanted to be able to, within our population, have an understanding of what was happening.

Q. I'd like now to turn back to Exhibit 6 in your stack. Actually, before we do that, one final question on drug utilization reports. Does the Medicaid agency receive drug utilization reports or other drug utilization information from its managed care plans? Is that something you get?

A. The reports that we just referenced actually includes the managed care plans, so for high-priority items, like the measures that mirror what we have in the OARRS database, we actually get that directly from Change Health. There's a lot of information -- a lot of work in compiling them. I'd have to check with the pharmacy team about the entirety of the reports that they receive from the plans.

Q. All right. So going back to Exhibit 6, I'd like to direct your attention to page 10. And on page 10 do you see that for several of the drugs, like hydromorphone HCL, it says "generic of" a brand name medication?

A. Yes.

Q. Does the Medicaid agency consider

the same factors for placing a generic drug on the preferred drug list compared to placing a brand name drug on the preferred drug list?

A. I'm not sure. I'd have to check into that detail with the pharmacy team.

Q. Is whether a generic drug is preferred or non-preferred related to the status of the equivalent brand name drug?

A. I'm actually not sure. There's an entire process related to that. I believe that is tied up in the rebate process that I'm not able to discuss.

Q. Is it fair to say that you're not the right person to discuss the details of sort of how these preferred drug lists are created with regard to generics versus brands and the sort of process that the pharmacy team goes through?

MR. PENDELL: Objection to form.

MR. SCHNIEDERS: Join.

MS. LINN: You can answer.

A. I'm not sure they're able to discuss that either, because information about rebates is protected.

Q. Excluding the rebate piece, I'm

trying to understand, as an example, you know, why hydromorphone HCL, a generic of a particular brand name -- why that generic is included but not the brand name itself in some situations, but sometimes the brand name is included, so the process in which those determinations are made.

Are you the right person to talk to about those issues or would that be someone else on your pharmacy team?

MR. SCHNIEDERS: Object to form.

A. Yeah. Likely Dr. Wharton would be the person to speak to.

Q. So just as an example, on page 9 of this exhibit, the 2018 preferred drug list, it lists MS Contin -- this MS Contin as a brand name drug of morphine sulfate ER tablet, but MS Contin itself is not included on the preferred drug list.

Do you see that?

A. So I see where you're reading that, yes.

Q. But to explain why that's the case, are you the right person to answer that question?

MR. SCHNIEDERS: Object to form.

A. No.
Q. No, you're not?
A. That's correct.
Q. And who would be the right person who could explain that?
A. Again, that would be my pharmacy team.
Q. If the Department of Medicaid covers a particular generic drug, does it cover all generic drugs that use the same active ingredient?
A. I actually don't know.
Q. And who would know that answer?
A. My pharmacy team.
Q. During the last deposition session, Dr. Applegate, we discussed the drug look-up tool and the list of drugs covered without prior authorization, which both are available on Ohio Medicaid's website.
Do you recall that?
A. Yes.
Q. And I believe you stated that you would need to check with the pharmacy team about how frequently they are updated.
Do you recall that?

A. Yes.
Q. Were you able to do that?
A. So I'm not sure that I did that. So I can likely make sure that my team has that information and they can get that to you.
MR. DOVE: We're going to definitely follow up with some of these questions with the department.
MS. LINN: If we could take like a one-minute, two-minute break.
MR. DOVE: Why don't -- we're going to take a break in about, I would say, a half an hour --
MS. LINN: Or give me one second. Your question is not pending anymore, right?
MR. DOVE: The question is not pending.
(Discussion had off the record between the witness and Ms. Linn.)
Q. Should I ask the question again?
A. That would be great.
Q. So do you have an understanding now about how often the drug look-up tool is updated?
A. Yes.

Q. And what is that understanding?
A. Weekly.
Q. Weekly.
Are you able to confirm whether the drug look-up tool includes all drugs covered by the Medicaid agency?
A. I believe so.
Q. And do you have an understanding now about how often the list of drugs covered without prior authorization is updated?
A. I would expect it to be at the same weekly interval.

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(Thereupon, Applegate Deposition Exhibit 26, Letter from Mary Applegate, M.D. to Dr. Bailit, dated October 13, 2017, Bates Numbered ODM_015989, was marked for purposes of identification.)

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Q. Dr. Applegate, I'm now showing you a document that's been marked as Exhibit 26. This document was produced by Medicaid agency and bears the Bates number ODM_015989.
Do you recognize this document?

A. I do.
Q. And what is it?
A. This is a letter of support to improve the models of care to try to improve better outcomes for pregnant women who have opioid use disorder.
Q. And this is dated October 13th, 2017, correct?
A. That's correct.
Q. And you're the signatory of this document, correct?
A. I am, yes.
Q. Now, you and Dr. Bailet were collaborating on a grant to study prenatal care for opiate dependent mothers, correct?
A. Yes. This was for the submission of the grant.
Q. And who -- well, first of all, was the grant approved?
A. I actually don't think so.
Q. Meaning it was rejected or it's still pending?
A. I would have to check with Dr. Bailet.
Q. If the grant had been approved,

where would the funding have come from?

A. This would have been federal funding.

Q. So I was going to ask, has Dr. Bailet's study concluded?

A. No.

Q. Has it even begun?

A. I'm not sure. We are doing -- I realize that may sound strange. We actually proceeded with trying to improve the coordination and the integration of obstetrical and opioid use disorder care even without the grant. So we are continuing to improve -- you know, trying to improve independent of federal funding processes.

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(Thereupon, Applegate Deposition Exhibit 27, Letter from Michael C. Barnes to Ohio Medicaid Pharmaceutical & Therapeutics Committee, dated June 25, 2010, Beginning Bates Number ODM_039341, was marked for purposes of identification.)

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Q. Dr. Applegate, I'm now showing you a document that we've marked as Exhibit 27, and I can represent to you that this has been produced by the agency in this litigation and bears the label ODM_039341 to 039342.

Dr. Applegate, do you see that this letter is addressed to the Ohio Medicaid Pharmaceutical & Therapeutics Committee from Michael C. Barnes at the Center for Lawful Access and Abuse Deterrence?

A. Yes, but let me comment this was from 2010, so I can't speak to the entire context of that particular time.

Q. My understanding is that you're here as a 30(b)(6) witness for the agency covering the years 2010 to 2013, so do you think you would be able to answer my questions on this document?

A. So I can try, depending on what the question is here.

MR. SCHNIEDERS: I would object based upon the designation in the letter that counsel provided.

MR. PENDELL: And I would also object based on the case law I just looked at in

this case, where when you notice a broad topic for a 30(b)(6) witness, a witness cannot be expected to anticipate and know the answer to every single question you're going to ask.

Q. Organizations like the Center for Lawful Access and Abuse Deterrence are able to submit letters to the P&T for consideration, correct?

A. Correct.

Q. And providers can do that as well, correct?

A. That is correct.

Q. And do you see at the end of the first paragraph the letter states that the P&T committee "will soon be evaluating for inclusion on the state's Medicaid formulary one or more opioid pain relievers designed to limit intentional abuse"? Do you see that?

A. Yes.

Q. And are those pain relievers also known as abuse-deterrent medications?

A. Yes.

Q. And this letter is dated, as we talked about, June 25, 2010. Was there a particular reason that the P&T committee was

considering opioid abuse-deterrent medications at that time?

MR. SCHNIEDERS: Object to form.

A. The P&T considers all the recommendations that are put forth to them.

Q. And do you recall a particular reason why they were considering abuse-deterrent opioid medications at that time?

MR. SCHNIEDERS: Object to form.

A. Again, I actually did not attend P&T so I actually cannot comment on that.

Q. And this letter asks the P&T committee to approve coverage of abuse-deterrent opioid medications, correct?

MR. SCHNIEDERS: Object to form.

A. It asks that we evaluate the inclusion in the state formulary for abuse-deterrent forms, yes.

Q. Just directing your attention to the first bullet point after the second paragraph, it states, "Prescription opioid abuse is an urgent public health threat that must be addressed immediately."

Do you see that?

A. Yes.

Q. And would you agree that by June 25, 2010 the Medicaid agency was aware that prescription opioid abuse was an urgent public health threat?

MR. SCHNIEDERS: Object to the form and foundation.

A. During my prior testimony I did note that it was around 2011 that we were aware that this was a problem.

Q. So would this document suggest that the agency was aware even earlier that the prescription opioid abuse was an urgent public health threat that must be addressed immediately?

MR. SCHNIEDERS: Object to form.

MS. LINN: Objection.

You can answer.

A. You know, the language I'm not sure everybody would agree with. I think what we were aware of is that more people were dying. I don't know that we were aware of everything that went into that. So certainly as a clinician, I actually do think it was clear around that time that we needed to pay more attention to prescription opioid medication.

I might add that as a clinician at that time, my focus was on trying to minimize any prescribing, not just switching to a different formulation of a dangerous medication. So the clinicians in general were focused on prescribing less, not just switching to different forms.

Q. Dr. Applegate, I'd now like to show you a letter that's been marked -- that I'm marking as Exhibit 28. It was produced by ODM and bears the Bates label 038848.

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(Thereupon, Applegate Deposition Exhibit 28, Letter from Margaret A. Scott to Michael C. Barnes, dated July 29, 2010, Beginning Bates Number ODM_038848, was marked for purposes of identification.)

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Q. I'd ask you to take a look at that letter and if you could tell me whether it would be accurate to say that this letter is the response that the Medicaid agency sent to Mr. Barnes from the Center for Lawful Access and Abuse Deterrence dated July 29th 2010.

MR. SCHNIEDERS: Object to the form, foundation.

A. So I read this. Now remind me what your question was.

Q. Would it be accurate to say that this letter is the response ODM -- or, excuse me. Would it be accurate to say that this letter is the response of the Medicaid agency, which was at the time the Ohio Department of Job and Family Services, that they sent to Mr. Barnes from the Center for Lawful Access and Abuse Deterrence?

MR. SCHNIEDERS: Same objections.

A. Yes. The timing of this suggests that this is the response to that letter, yes.

Q. And in the second to last paragraph are the long-acting opioids available without prior authorization, morphine, sulfate ER, fentanyl patch, Kadian and OxyContin. Are those abuse-deterrent opioids in your view?

MR. SCHNIEDERS: Object to form.

A. No, they are not.

Q. And so would it be accurate to say that this letter is stating that coverage of abuse-deterrent opioids was considered but not

approved by the Medicaid agency and P&T committee?

MR. SCHNIEDERS: Object to the form and foundation.

A. Yes, as part of PDL, but I will note that there's a process to receive non-preferred drugs, so you must ask for it and fill out a piece of paper and have a discussion with the managed care plans. So it would not be true to say that there was zero access to abuse-deterrent forms.

Q. And was that process in place in 2010?

A. Yes, it was.

MR. DOVE: I think now would be a good time for us to take a break.

THE VIDEOGRAPHER: Off the record, 10:58.

(Recess had.)

THE VIDEOGRAPHER: We're back on the record, 11:21.

EXAMINATION OF MARY APPLEGATE, M.D.

BY MS. HAN:

Q. Dr. Applegate, my name is Anna Han and I represent McKesson in this litigation. We

met at your last deposition and I'll be asking the next set of questions.

So both you and Dr. Wharton testified that ODM has data analysts on staff; is that correct?

A. That is correct.

Q. Have the data analysts or any other researchers been used to obtain and analyze data related to opioid utilization and prescription trends?

A. Yes. Not all of that has been by specific data analysts within the agencies. Some of that work has been done by research partners.

Q. And who are those research partners?

A. The majority are through the Government Resource Center, who is tied to the Ohio State University.

Q. Do you also rely on analysts from Change Healthcare?

A. Yes, as you saw in the prior report.

Q. Does the Medicaid agency also rely on analysts from the managed care plans?

A. We get reports from the managed care plans, and they must have an analytic staff that

actually does that work for them, yes.

Q. And have the researchers and analysts at the Medicaid agency also analyzed claims data for other projects unrelated to opioid prescriptions?

A. Yes.

- - - - -

(Thereupon, Applegate Deposition Exhibit 29, One-Page Document Entitled "Overview of Opioid Prescribing Metrics," Bates Numbered ODM_016480, was marked for purposes of identification.)

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Q. I'm going to show you the next exhibit marked 29. This is a document that was produced by ODM in this litigation. The Bates number is ODM_016480.

Dr. Applegate, do you recognize this document?

A. So I recognize the content of the document, yes.

Q. And what is the content of this document?

A. This is a description of the

opioid-related metrics that exist in OARRS, which is our prescription drug monitoring program.

Q. And this document is dated with a revision date August 20th -- I assume that's a typo -- 2013.

A. I think I would presume that -- it's 2103, so far into the future, so I would presume, so yes.

Q. Do you know if there have been any updates to the content of this document?

A. I would have to talk to my colleagues at the Board of Pharmacy to see if there were any methodology revisions. This simply notes the numerator and denominator in each of the measures but does not necessarily specify the time spans, 90 days, 120 days. So there's additional methodology that actually may go with this, but the -- the title of the measures actually still exist.

Q. What are the opioid-prescribing metrics intended to assess?

A. Broadly, they're intended to assess overall utilization of controlled substances, so not just opioids in particular but controlled

substances, and when we developed these metrics several years ago, we were focused on an understanding of what was happening in Ohio at a population level as well as specific points that might be particularly dangerous as it relates to being at risk for overdose or death.

Q. And just to make sure I understand, for the first two prescribing metrics here, they're related to controlled substances generally, not specifically opioids; is that right?

A. That is correct.

Q. So I just want to go through these six metrics.

Why is it important to know the percentage of prescribers of controlled substances registered on OARRS?

A. So I think there's an underlying strategy here, and that is -- or a few assumptions.

One of the assumptions is that one of the reasons there were so many patients with many prescribers and pharmacies related to the fact that their care was not coordinated, and so checking the OARRS database was a way to let the

clinicians know who else was involved in the care of that patient because the patients were not always certain or forthcoming with that information.

Q. And the second metric, the percentage of registered prescribers of controlled substances using OARRS, is it accurate to say that not every registered prescriber actually uses OARRS in his or her practice?

A. So part of history is that only certain prescriptions required like mandatory checking of the PDMP, the OARRS system. So specifically, if you had a patient on over 80 morphine equivalents for more than three months, you know, by law you actually had to check OARRS. In emergency departments, for example, you might just be giving a day supply or a two-day supply and you would not be required to check OARRS. So you can have somebody who is a prescriber, who actually may not be registered, because the nature of that prescription did not meet the level of the law.

Q. Is it correct that there are registered prescribers on OARRS who don't

actually use OARRS, though?

MR. SCHNIEDERS: Object to the foundation.

A. Actually, to register means that -- you have to look at OARRS to be registered, so I think what this gets to is the total number of prescribers and then the total number who are actually using OARRS.

Q. Right. So I'm trying to understand the distinction between the first two points. The first one is measuring the percentage of prescribers registered on OARRS and then the second is measuring the percentage of registered prescribers using OARRS. So is there no distinction there?

A. So I read this differently.

The first one is the percentage of prescribers that prescribe controlled substances. So what happens is there are plenty of providers who actually don't do any controlled substances, maybe related to their specialty. For example, a neonatologist I would not expect to actually be prescribing controlled substances, for example, or if their practices are constrained to an in-hospital system, that

actually would not show up on the OARRS database. So what happens, though, is when there's a prescription for a controlled substance that somebody brings to a pharmacy, that's actually -- that script is actually what gets registered in OARRS. So all prescribers of outpatient control medications, all those drugs are actually registered in OARRS or are -- that data is actually in OARRS whether or not -- the script -- the drug data is in there. Whether or not the prescriber has to register and use OARRS is something different.

So the example I gave was if you're just prescribing one pill after you had all your wisdom teeth removed, that would not require by law that you actually check OARRS, but that prescription will be in OARRS. So one is the prescription itself and the other one is those who are actually registered and taking care of patients where it's required.

Q. I see. Thank you.

Why is it important for the Medicaid agency to know the proportion of patients at AD, MED, morphine equivalent dose, and above who have at least one OARRS inquiry over a specific

time period?

A. That is directly linked to the requirement in law that I just referenced, and so we're actually checking for adherence to the law.

Q. Is that also the case for the fourth metric, number and percentage of patients prescribed both sedatives and opioids?

A. Yes. I think there's been an evolution over time. At this time we actually think part of the assessment of the patient is that every single controlled substance is -- should -- you know, we should check OARRS as part of the prescribing process, and I think that's much of what you've seen in the 5,000-fold increase in those who are registered and checking OARRS. But yes, these are consistent with the state guidelines that I referenced earlier.

Q. And the increase you just mentioned in using OARRS, what is the time period that that increase has occurred?

A. Since 2012. That data is actually in the annual OARRS report that I just referenced, and that has been tightly associated

with an 89 percent drop in doctor shopping, which is the going -- you know, having prescriptions from four or more clinicians and having them fill it at four or more pharmacies. So, again, you know, to my earlier point, this -- these are measures that support the underlying strategy of trying to do a better job in coordinating care.

Q. And the fifth metric, "Percentage of prescriptions filled with a quantity of 120 plus capsules or pills per prescription," is that also linked to a legal requirement?

A. It is linked to the guideline in that we need to prescribe the smallest amount in the shortest duration in order to meet the need of the patient.

Q. And, finally, the average MED per prescription metric, is that also linked to a legal guideline?

A. Yes, it is.

Q. And has ODM been tracking the change over time of these metrics?

A. Yes. As you saw in the Change Healthcare report, you actually note the trends in time specifically for the Medicaid population

as opposed to what OARRS has, which is all payers and all prescriptions in the state for all populations.

Q. Does ODM rely on Change Healthcare for that information without its own analysis?

A. So Change Health is one group of analysts that actually looks at the data. I referenced earlier that we have research partners who are also helping us with this.

Q. At your last deposition you testified about a CDC reference that was cited in the Ohio Prescribing Guidelines for Chronic Pain?

A. Yes.

Q. Were you able to find that reference?

A. Yes.

Q. And did that reference clarify whether the opioids mentioned were necessarily prescription opioids?

MR. SCHNIEDERS: Object to the form.

Go ahead.

A. Yes.

Q. So if so, did it clarify whether the prescription opioids were legitimately

prescribed?

MR. SCHNIEDERS: Object to the form.

Go ahead.

A. The report discussed the nature of the opioid epidemic at that time, including the connectivity to prescription medications kind of opening the door to future illicit use that then led to either fatal or non-fatal overdose. It also noted that the Medicaid population may be at higher risk for opioid utilization as well as overdose, and that's actually what prompted a lot of the agency's efforts, that then realized a 40 percent reduction in prescriptions for opioids. So it did highlight the national problem related to opioids.

Q. Right. So as I understand it, the reference was focused on prescription opioids?

A. Yes.

Q. My question is, did the reference clarify whether those prescription opioids were prescribed based on legitimate medical prescriptions?

MR. SCHNIEDERS: Object to the form.

A. So there's a judgment there as to what's legitimate. All of the guidelines are

around medical necessity and safety, so legitimate is a judgment and separate from what we think of as medically necessary.

Q. So would it be accurate to say that the guidelines discussing prescription opioids were referring to prescription opioids that were prescribed based on medical necessity?

MR. SCHNIEDERS: Object to form.

A. Yes.

Q. Are you familiar with the CDC prescribing guidelines that were issued in 2016?

A. Yes.

Q. Is Ohio Medicaid required to follow the CDC guidelines?

A. In Ohio everyone is required to follow Ohio's state guidelines, which are actually stricter than the CDC's guidelines. The CDC did not include children and we are aware that those under 18 are at higher risk for future addiction.

In addition, the CDC guidelines really had a focus on primary care clinicians, and in Ohio we actually include all clinicians. So in Ohio they are required to follow Ohio law, which is stricter than the CDC guidelines.

Q. At the time in 2016 that the CDC guidelines were issued, did Ohio Medicaid already have stricter guidelines?

A. Yes.

Q. Did Ohio Medicaid have any concerns about how strict guidelines could be detrimental to individuals with chronic pain?

MR. SCHNIEDERS: Object to the form.

Go ahead.

A. There was an entire separate body of work related to individuals who had chronic pain. As I testified before, patients with chronic pain cannot be equated to those with acute pain. They may develop tolerance and dependency, and they also may have really severe conditions that are problematic. So I think it's easy to just develop a rule that says no more than -- I'm making this up -- no more than three pills for anybody under any circumstance, and the medical profession really is dedicated to alleviating suffering and curing people, but it actually is with safety in mind.

So I'm not sure if that addresses your question.

Q. Yes. So I'm going to mark the next

document as Exhibit 30, and this is a document that's been produced by Ohio Medicaid in this litigation. The Bates numbers are ODM_027015 to ODM_027016.

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(Thereupon, Applegate Deposition Exhibit 30, Two-Page Document Entitled "Opioid Guideline Feedback," Beginning Bates Number ODM_027015, was marked for purposes of identification.)

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Q. Dr. Applegate, do you recognize this document?

A. I do.

Q. What is it?

A. A long time ago -- actually, this is dated in 2018, but this is feedback from the opioid guideline. I'm actually not sure who produced -- like who wrote this document, but we, since the beginning of GCOAT, had a professional education committee that started the whole process of developing guidelines for the State of Ohio. It's a very broad group that included emergency room physicians, primary care

clinicians, subspecialists, pain medicine docs, those in addiction treatment; and as we tried to delineate the key points of the guidelines, we actually did receive input from this larger group in a variety of formats, both verbally, and in this case it actually looks like somebody wrote the specific input from key members of that group.

Q. At the top of the document where it says, "Opioid Guideline Feedback," what opioid guidelines was that referencing?

A. So I'm actually trying to decide which ones these might be because a lot of the content actually could apply to more than one. But based on the date, I actually think this is connected to -- I think there are a number of subjects that are encompassed in here because I think this is for acute pain but they reference the chronic pain rule so I'm actually not sure.

Q. Okay. Right under that first heading, do you know who Ted Wymyslo is?

A. Yes. He used to be the prior director of health and now is in charge of the Association of the Federally Qualified Health Centers.

Q. When you say he was the director of health, was that for the Medicaid agency?

A. Let me think about this. I actually don't remember relative to when we became a stand-alone agency. I would have to look up his dates of service in that capacity.

Q. Sure.

But he's no longer working for the state; is that right?

A. That's correct.

Q. And then going about halfway down the page, the bold "APNs," do you know what that means?

A. Advanced practice nurses.

Q. And so who -- are MF and JS initials?

A. It likely references APNs that may have been in discussion.

Q. Okay. Do you know who they are?

A. I'm not sure. I think I know hundreds of APNs.

Q. And then at the very bottom, do you know who Dr. Ports is?

A. I think he's a primary care clinician.

Q. Is he affiliated with Ohio Medicaid?
A. No. I think he was part of the group.
Q. And on the second page, Dr. Justin, do you know who he is?
A. Again, there are -- there are many, you know, including in and out-of-state government, so actually -- I don't actually recall.
Q. Okay. And Dr. Bechtel, do you know who that is?
A. He's a clinician from the State Medical Board.
Q. Okay. Going back to the first page under the Ted Wymyslo heading, the third from the bottom in his section, there's a statement that says, "Access a concern - as the list of financially and administratively undesirable patients grows (not just pain med doc access - but PCPs willing to treat)."
Do you have an understanding of why access would have been a concern?
MR. SCHNIEDERS: Object to the form and foundation.
A. You know, these are -- these are

just notes from a broader conversation, so I'm not sure that I understand the entirety. I think the suggestion here is that if we have so many rules, then patients who actually have pain will not have access to relief, and if we have so many administrative requirements, primary care clinicians will be unwilling to treat Medicaid patients, especially if they have pain conditions.

Q. Do you know if the guidelines -- whichever guidelines which were being discussed ultimately addressed this concern?

A. Well, there was this entire group process, and, actually, there was a discussion related to the need to ensure access to high quality care that included safety as part of the objective.

Q. Do you know what the outcomes were of that discussion?

MR. SCHNIEDERS: Object to the form.

A. I'd have to check the dates, but the -- after we wrote the acute pain guidelines, we actually developed limits, so if you're a grown up and you have acute pain, you're not allowed to exceed a seven-day duration of your

prescription limited to 30 morphine equivalents or less unless you have additional documentation to support why that's appropriate. So it's seven days for adults and five days for children. And some of that may be part of what prompted this conversation. So, again, this is actually somewhere in the spectrum of all of these guidelines, so I'm actually not sure about any additional detail.

Q. Those acute pain limit guidelines that had the limits that you mentioned, when were those limits put in place?

A. So I'd have to check for the final date. My thought was that it was in late '17. I think it was in '17.

Q. Are those limits something the Medicaid agency had the capability to implement before 2017?

MR. SCHNIEDERS: Object to the form.

A. What we did was whenever we were -- you know, this is a process. When you come up with guidelines, it's actually a process. So we didn't wait until everything was final to start working with the plans to make sure they could plan to put edits in place because everything

takes time. So I think the idea that we should pay attention to morphine equivalents and to the duration of the script actually was an ongoing conversation over this period of time.

And periodically we do want to keep in touch with the clinicians related to what's the impact of it, were there any inadvertent consequences, did we create issues that were not clear at the time the initial guidance was written. So even now we're actually in touch with clinicians to be sure that we're all kind of working towards the same purpose, which is really to eliminate all opioid-related drug deaths.

Q. On the first page of that same document, under the APN's heading, there's a line that states, "Worried about pushing to heroin," and then on page 2, under the Dr. Bechtel heading, it appears Dr. Bechtel was asking if -- if we know if overshooting with primary care docs so that patients are moving to illicit sooner and getting caught in the fentanyl lacing bubble.

What is your understanding of those concerns about illicit opioids?

MR. SCHNIEDERS: Object to the form.
MR. PENDELL: Same.
THE WITNESS: So I can answer that?
MS. LINN: Yes.
THE WITNESS: Okay.
A. So the issue there is that if patients are suffering and they're not allowed to get pain medications even under reasonable circumstances because of fear that the clinician's license will be yanked by the state medical board for not adhering to state guidelines, that somebody who ordinarily would not consider obtaining pain medications illicitly might actually do so. So that was actually the concern. So the way that we monitor this is we actually track what's happening with prescription drugs and then we track what's happening not just with deaths but in conjunction with the Department of Public Safety. We're actually monitoring their view of what's happening with illicit use.
Q. When you say you track the prescriptions and the deaths, that's the Medicaid agency conducting its own analysis?
A. No. Again, this is in partnership

with the agencies that actually have the data. So in this case it's the Department of Health that actually has all vital stats, statistics.

Q. What does the Ohio Medicaid agency do with the information that it gathers from the other agencies?

A. So it's a collective impact model. I think it helps give us an awareness so that we can keep thinking about how to do a better job. So in recent years, as we've seen the trend in prescriptions drop dramatically -- so 40 percent is really a dramatic drop -- we've had a parallel effort related to screening early intervention and effective treatment for opioid use disorder in addition to attention to ensuring that alternatives to opioids are available not just on the front end with acute pain but also along the entire chronic pain journey.

So to that end, as I mentioned in my earlier testimony, the department did begin the benefit of acupuncture. We already had massage, physical therapy and other modalities available. And we also increased the opportunity for new provider types, including chiropractors and

acupuncturists, to provide these alternative therapies.

Q. Going back to the CDC guidelines for a minute, are you aware that over 300 medical experts have signed on to a letter to the CDC that expresses concern about the misuse of guidelines to deprive chronic pain sufferers of much needed medication?

MR. SCHNIEDERS: Object to the form. Foundation. Also beyond the scope of the notice for this deposition.

MR. PENDELL: Same.

A. Yes. Actually, I am aware of that. I will note, however, that other states have even stricter requirements, and I'm unaware as to the percentage of the delegation that actually represented any clinicians in Ohio.

Q. Are you aware of instances in Ohio where a Medicaid patient was denied medication by a doctor because of the Ohio prescribing guidelines?

A. I am not; however, I will note that the guidelines simply say not that there's no access but that the clinicians must document the reason that they're exceeding the guidelines.

Q. You sponsored an ODM project to limit prescribed opioid doses through standardized plan efforts; is that right?

MR. SCHNIEDERS: Object to the form.

A. Yes. As I mentioned earlier, we did gather all the pharmacy directors to ensure that they put edits in place to adhere to state guidelines.

MS. HAN: I'd like to mark as Exhibit 31 a document produced by ODM in this litigation. The Bates numbers are ODM_034210 through ODM_034224.

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(Thereupon, Applegate Deposition Exhibit 31, Multi-Page Document Entitled "Limiting Prescribed Opioid Doses Through Standardized Plan Efforts," Beginning Bates Number ODM_034210, was marked for purposes of identification.)

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Q. Do you recognize this document?

A. Yes, I do.

Q. And what is it?

A. So as part of our effort to do a

better job taking care of people, we have trained internal people in the department in very specific processes that more reliably get us results. So this is a field called implementation science, and what we have here is a document delineating one of those quality improvement efforts.

Q. Who is Katie Weiskirchner?

A. I'm actually not sure -- I'm actually not sure who she is.

Q. If you'll turn to the second slide where it says the "Aim of the Project."

A. Yes.

Q. Do you see that the aim of the project was to decrease Ohio total and managed care plan-specific solid opioid doses by 30 percent by December 31st, 2017?

A. Yes.

Q. What steps did the pharmacy team listed on the front of this presentation take to reach that goal?

A. So very specifically, this is Dr. Wharton's project, so I can tell you about it, but I know you spoke to him as well.

As you will note on page 5, actions

were undertaken to have the managed care plans support both patient education as well as provider education to be sure that it was specific enough to actually fall in line with state guidelines, and to put in place some of the efforts that I referenced earlier as it relates to quantity limits and monitoring morphine equivalents, et cetera.

Q. Do you know if the goal described in this presentation was achieved?

MR. SCHNIEDERS: Object to form.

A. Let me check over the period of time.

So I don't know that there's a percentage. There's this dramatic drop that you see on the page that ends in 16. I can tell you that over the period of time there's been a 40 percent drop within the Medicaid program. So since I can't see the exact date on this, it's not clear.

When we've looked at managed care plan activity, we actually do follow the same rate of improvement as the state as a whole has.

Q. Would you agree that it wouldn't be improper for a provider to prescribe opioids

pursuant to the ODM guidelines to a patient with a legitimate medical need?

MR. SCHNIEDERS: Object to the form.

A. No. That would be fine.

Q. And would you agree that it wouldn't be improper for a pharmacy to dispense the opioids designated in that prescription?

MR. SCHNIEDERS: Object to the form.

A. That's correct.

Q. And it would not be improper for ODM to reimburse for those particular opioids?

MR. SCHNIEDERS: Object to the form.

A. That's correct.

Q. Now, if the patient receiving those opioids then sold those opioids to somebody else, would ODM have any responsibility for that sale?

MR. SCHNIEDERS: Object to the form.

MR. PENDELL: Objection to form and beyond the scope.

THE WITNESS: So am I allowed to address this?

MS. LINN: It's outside of the scope of their topics, but you can answer in your personal capacity.

A. So we actually -- so this is called diversion, and we actually monitor a number of things that actually look for that.

So one of the ways that we think that's happening is by going to four pharmacies, having four different prescribers. So the layperson term is doctor shopping. So we actually do watch for that. We watch for escalations of doses without a change in clinical condition. And we listen to clinicians who suggest that there actually may be a concern.

The pharmacy benefit for the Medicaid program is meant to be for the beneficiary, so we do have some of those processes in place to ensure that that, in fact, is the case.

Q. If a patient is diverting, is it the pharmacy's responsibility to know about that?

MR. SCHNIEDERS: Object to the form. Foundation. Also, calls for a legal conclusion.

MR. PENDELL: Join.

MS. LINN: Objection. In either capacity she wouldn't be able to answer that question.

Q. Is it correct that Ohio Medicaid has a coordinated services program?

A. Yes.

Q. And that coordinated services program requires members with certain indicators of unsafe drug use to participate in the program?

A. That's not entirely correct because the patients actually have a choice, but the plans do have criteria that would make them eligible for such a program and we encourage the managed care plans to enroll patients in that.

Q. And what is the goal of the coordinated services program?

A. So the layperson's term for this is lock in, as we've talked about, so that all of the controlled substances are actually filled at the same pharmacy so that there's a view at the point of the service of the entirety of the safety of the medication regimen that the patient may be on. With this comes a care management function on the part of the managed care plans, and they work to coordinate care among different provider types.

We've found that this has been

successful and has been associated with almost a 30 percent drop in morphine equivalents and better utilization of health services for routine care, so, for example, less emergency department use because they're actually connected to a routine source of care.

Q. You said that those beneficiaries who are eligible for the coordinated services program can choose whether or not to participate. Do you know what percentage of beneficiaries who are eligible are actually enrolled?

A. No, not offhand.

Q. Do you know if there's a limit on how many beneficiaries can participate in the coordinated services program?

A. I can't think of a reason there would be a limit, but again, the patients may have a number of reasons or restrictions or circumstances. So what happens is we may see the pharmacy data and there actually may be clinical reasons we're seeing that pharmacy pattern.

So, for example, if we have a patient who has to go to a quaternary center for

very specialized surgery or specialty care, they may -- they may get a prescription there, they may stay nearby for a while to get follow-up and then actually go home. If they have a reaction to the initial prescription, let's say nausea or it's too sedating or something like that, they may get another one actually when they're home. And so there could actually be legitimate or medically necessary reasons that you actually may see the pattern that we see on the pharmacy side without it actually being an indication of diversion or addiction. So the reason that program happens is so that someone else can actually help with all of that coordination to ensure that the patient is safe.

Q. Is there a way for ODM to distinguish between the -- someone in the example that you mentioned and someone who is diverting?

MR. SCHNIEDERS: Object to the form.

A. So with this function is care management, and so the only way that you can know is actually knowing that level of detail at the person level, which needs to happen close to the patient.

Q. And who is responsible for going through the care management -- who's responsible for having that relationship with the patient?

MR. SCHNIEDERS: Object to the form, foundation.

A. The program runs largely through the managed care plans, who then have relationships with the clinicians in their panel.

Q. Do you know what the Ohio Opioid Analytics project is?

A. Yes.

We have a partnership with the Government Resource Center for a number of research topics, one of which is predictive modeling for patients with opioid use disorder or opioid use in general to try to predict who's at risk for misuse, abuse and fatal and non-fatal overdose.

Q. When did ODM become involved in the opioid analytics project?

A. I'd have to look at documents. It seems like maybe approximately 18 months ago.

Q. Do you know when the opioid analytics project was first discussed?

A. When we set it up. So we're

actually the funders for the project.

Q. So about 18 months ago?

A. Yes. I'd have to look at an exact date. It might be -- it's possible it was two years ago.

MS. HAN: I'm going to mark as Exhibit 31 a document produced by ODM -- sorry, 32, a document produced by ODM in this litigation. The Bates number is ODM_022801 to ODM_022802.

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(Thereupon, Applegate Deposition Exhibit 32, Multi-Page Document Entitled "Ohio's State Innovation Model: Using Episodes of Care to Impact the Opioid Crisis (and Other Public Health Priorities), Beginning Bates Number ODM_034768, was marked for purposes of identification.)

- - - - -

Q. Do you recognize this document?

A. Not necessarily specifically, although the content is familiar to me.

Q. If you turn to page 2, you'll see there's a timeline for deliverables at the

bottom.

A. Yes.

Q. And it states, "December 15th, 2018 - GRC submits draft tools and draft report for state sponsor review."

Is Ohio Medicaid the state sponsor?

A. Yes, as well as the Ohio Board of Higher Ed, as it notes in the first paragraph.

Q. Right.

So by December 15th, 2018 did Ohio Medicaid and the Ohio Department of Higher Education receive the draft report from the GRC?

A. Yes.

Q. And what information did that include?

A. So -- so this becomes complex. There are a series of logistics regression analyses that go into every risk factor that they actually look at and we need to see how well the model fits. They measure the area under the curve. They apply a number of statistical tests. So it was really all that math and science that actually was presented at that time. The model was not refined enough or actually good enough for them to have something

that we could show in public with dashboards in that real-time visualization, as is described on the first page. So this is still under development and they're refining it at this time.

Q. Do you know if the GRC is on track to meet the other deliverables on this timeline?

A. So I know we're meeting with them again. We did ask them to go back and make adjustments, so I'm not sure if the -- if this particular timeline reflects the adjustments we asked them to make.

Q. Next I'd like to show you an exhibit that will be marked as 33, and this was produced by ODM in this litigation with the Bates numbers ODM_034768 to ODM_034780.

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(Thereupon, Applegate Deposition Exhibit 33, Office of Health Transformation Document Beginning Bates Number ODM_034768, was marked for purposes of identification.)

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Q. Do you recognize this document?

A. Yes.

Q. What is it?
A. This is a document from the Office of Health Transformation describing efforts underway to consider safety in opioid prescribing as part of how we pay for high value in healthcare.
Q. And what is ODM's involvement in this innovation model?
A. We're the implementing entity.
Q. If we turn to slide 7, there's a description about dentistry?
A. Yes.
Q. The slide states that dentists -- the first bullet point in the dark box states that "Dentists make up 4 percent of unique opioid prescribers in Ohio, but write 8 percent of the total opioid prescriptions."
Has ODM made any dentist-specific recommendations related to opioid prescribing?
A. So I'm not sure that ODM did this. I think as part of our larger GCOAT, it was recognized that all prescribers could be part of the solution, and at the time we had written 43 different episodes of care. So I want to make sure we keep this in context. So we had

headache, low back pain, hysterectomies, newborn deliveries, newborn infections, heart failure, joint replacements, you know, 40 different episodes. And we involved all provider types, surgeons, primary care docs, pediatricians, geriatricians, but not dentists. So one of the points that was made at this time was we could widen the circle of clinicians who could actually help us with this problem by including a dental episode of care related to tooth extraction.

Q. If you turn to slide 9, in the graphic on the right, is that showing that 36 percent of total patients prescribed opioids with one or more risk factors are developing -- had one or more risk factors for developing opioid use disorder --

MR. SCHNIEDERS: Object to the form.

Q. -- during that particular time period?

MR. SCHNIEDERS: Same objection.

A. Yes, that is correct, and the risk factors are what are actually listed here, which include having behavioral health diagnoses, et cetera. So yes.

Q. Are the four risk factors listed on this slide the only risk factors for opioid use disorder?

A. No.

Q. Would you say that they are the main risk factors?

MR. SCHNIEDERS: Object to the form.

A. You know what, I actually don't know the entirety of the methodology behind this. This clearly has a focus on those with behavioral health conditions.

Q. Are there any restrictions in place regarding prescribing opioids to someone with one or more risk factors for opioid use disorder?

MR. SCHNIEDERS: Object to the form.

A. So the guidelines are that we do an assessment of risk factors, and that's one of many variables that go into ensuring that the prescriptions are safe.

Q. And if you turn to slide 12, you'll see there's a timeline shown on that slide.

Is the Medicaid agency on track with the reporting timeline shown here?

A. Yes, we are.

MS. HAN: I think that is all that I have. Thank you.

MR. SCHNIEDERS: Counsel, do you want to take a quick break?

MR. DOVE: Just a quick break.

THE VIDEOGRAPHER: Off the record, 12:10.

(Recess had.)

THE VIDEOGRAPHER: We're back on the record, 12:26.

FURTHER EXAMINATION OF MARY APPLEGATE, M.D.

BY MS. HAN:

Q. Dr. Applegate, I just have a few more questions.

Earlier when we were discussing the ODM activities related to diversion, you mentioned that ODM looks for doctor shopping, escalating dosages without a change in condition and whether a clinician has expressed concern; is that correct?

MR. SCHNIEDERS: Object to the form.

A. Yes. There may be additional factors, but those are a few.

Q. And if ODM has not observed the doctor shopping, escalating dosages without a

change in condition and no clinician has expressed concern but a beneficiary has still diverted the prescription medication, you would agree that ODM doesn't bear responsibility for the diversion?

MR. SCHNIEDERS: Object to the form, foundation. Also, calls for a legal conclusion.

A. I'm not sure I can answer something about which we know nothing, so we may not know that information.

Q. Right.

So if ODM doesn't know about it, would you agree that ODM is not responsible for what happens to that medication?

MR. SCHNIEDERS: Same objections.

A. I actually don't know how to answer that.

Q. And, again, earlier when we were talking about the opioid policy or opioid guidelines, you stated that managed care plans work with the point of sale -- work with the point of sale to implement the policy. What did you mean by that?

A. That's actually connected to my comments about the edits that they put in place;

so, for example, there are quantity limits, they might have step therapy requirements. Right at the point of sale there are a number of edits that are in place before that prescription can be filled. So that's actually how we ensure that we have processes in place to make sure that we're supporting the state guidelines.

Q. Who is actually putting those edits in place for the quantity limits? Is that the managed care plans requiring that?

A. In conjunction with their pharmacy partners. I'm sure they have to have analysts who have to code it and their IT people to actually make it happen. I'm sure they have a team to go through the whole process.

Q. One of the last documents that I showed you had a reference to opioid use disorder. With respect to opioid use disorder, does the Medicaid agency differentiate between beneficiaries who are addicted to prescription opioids and those who are addicted to illicit opioids?

MR. SCHNIEDERS: Object to the form.

A. Not necessarily specifically because that information may not be known to us. We

don't necessarily know who may have illicit use. Illicit use can happen at the same time as prescription drug use. So all we know is that diagnosis from a claim.

Q. Have you ever been involved with any task forces or action teams or similar groups concerning drug use?

A. In my prior testimony I noted to you that there was a task force prior to GCOAT. I actually couldn't quite remember the name. It was at a time that the Department of Drug and Addiction Services was separate from the Department of Mental Health. So that was a task force. I mentioned the groups within GCOAT as well. And I'm not sure that we have other formal task forces per se, but I'm sure you're aware that around the country there are many groups who are trying to get their arms around promising best practices as it relates to this issue, and the agency certainly has participated in those.

Q. So the task force that you referenced prior to GCOAT, that was also focused on opioids?

A. Yes.

Q. What is your understanding of the purpose of these types of task forces as they relate to opioids?

MR. PENDELL: Objection to form.

MR. SCHNIEDERS: Object to the form.

A. The primary purpose was to address opioid-related deaths specifically as they relate to prescription medications. As time went on and we made progress in that area, we're trying to address the totality of opioid use disorder even beyond prescription medications, so very specifically, when we treat patients, we will treat patients if they have illicit use and try to help them get to recovery just as much as we would treat folks who actually have prescription medications as their cause.

Q. And when you say we will treat patients if they have illicit use and try to help them just as if they were actually having prescription medications, do you mean that ODM treats beneficiaries who have illicit use the same as if they had prescription medication?

MR. SCHNIEDERS: Object to the form.

A. What I mean is if they have that diagnosis, we will treat them independent of

where they received their opioids.

Q. I just want to clarify. You're saying ODM will treat them the same?

A. We pay for services for opioid use disorder. Just stop the sentence there. We actually don't discriminate related to the -- how the person got to that condition.

Q. So you stated that the primary purpose of the task forces is to address opioid deaths. Do the task forces conduct investigations into the cause of death?

MR. SCHNIEDERS: Object to the form.

A. The Department of Health is the only one who actually has more specific data related to the causes of death, and not all of that is public. I believe coroners and perhaps like child fatality review forums may have additional information and additional activities related to causes of death.

Q. Do you know if the task forces investigate drug manufacturers?

MR. SCHNIEDERS: Object to the form.

A. I'm not aware.

Q. Do you know if they investigate drug distributors?

MR. SCHNIEDERS: Object to the form.

A. I am not aware. The focus really was on what the agencies were able to do about the problem, so it was really more focused on best evidence practice, making sure that we had an adequate treatment provider network, making sure that everybody followed safe prescribing guidelines, making sure that patients had choices in the types of treatment they received, making sure there were adequate psychosocial services as well, and addressing any other barriers, like transportation.

Q. Have you heard of the Ohio Prescription Drug Abuse Task Force?

A. I'm not sure that's a totally specific thing. I think what I described may have been one. I know that local communities also have coalitions. So there could be 80 such task forces locally. So I'm not familiar with the names of all of them.

Q. Does ODM have involvement with the local task forces?

A. The main state agency that oversees that and pays attention to what is going on at that level is the Ohio Department of Mental

Health and Addiction Services.

Q. Does that mean that ODM is not involved with the local task forces related to opioids?

MR. SCHNIEDERS: Object to the form.

A. We have members within the agency who are liaisons to the other agencies and may participate -- may have some level of participation at the local level, but in the entirety of our work related to this, that's not the most prominent part.

Q. Do you know who those members who are liaisons are?

A. I think over the years they have changed as personnel has changed.

Q. Do you know who they are today?

A. I can get you the names specifically.

MS. HAN: That is the end of my questioning, but I believe we have another attorney for the Defendants who will question.

THE VIDEOGRAPHER: Off the record, 12:36.

(Short recess had.)

THE VIDEOGRAPHER: We're back on the

record, 12:37.

EXAMINATION OF MARY APPLEGATE, M.D.

BY MS. O'GORMAN:

Q. Good afternoon, Dr. Applegate. I just have a few questions for you. My name is Debra O'Gorman. I represent the Purdue Defendants in this action.

Does the ODM have a predetermined standard for determining medical necessity of prescriptions that it covers?

MR. SCHNIEDERS: Object to the form.

A. The definition of medical necessity actually is coded in law.

Q. Is that a federal law?

A. It's a state law. I'm unaware of a federal law related to that.

Q. Are you familiar with that definition?

A. Not verbatim, but I understand the content, yes.

Q. And does the standard for medical necessity apply to managed care organizations that provide coverage to Medicaid patients?

A. It applies to all aspects of the Medicaid program, so managed care and fee for

service.

Q. Are you aware of ODM reimbursing for any opioid prescriptions that were not medically necessary for the persons for whom they were written?

A. I am not.

Q. So then if ODM was aware that an opioid prescription was not medically necessary for the patient for which it was written, it would not reimburse for that prescription, correct?

MR. SCHNIEDERS: Object to the form.

MR. PENDELL: Objection.

MS. LINN: Objection.

THE WITNESS: Can I answer that?

MS. LINN: Yes.

A. Yes.

Q. If the ODM became aware of a prescription that was written that was not medically necessary, what actions would be taken?

MR. PENDELL: Form.

MR. SCHNIEDERS: Same objection.

A. So this is an interesting question because the medical establishment really focused

on what they knew within the walls of their offices and hospitals, and we did not have greater insight into what might be happening outside of that until we started seeing the data, and then it was in conjunction with the medical community, patient stakeholders and task force, for example, that we really refined what we understood was required for a whole variety of procedures and for pain control. So over the period of this time the field of pain management actually has evolved to actually being a safer -- you know, a safer field.

Q. And what period of time would you assign to this course of --

A. The last several years. Certainly since the time frame we're talking about, you know, around 2011 or so.

Q. I don't think you answered my question.

Are you able to tell me what ODM would do if it became aware that a prescription was written that was not medically necessary, what actions would be taken in that instance?

MR. PENDELL: Objection to form. Calls for speculation.

MR. SCHNIEDERS: Object to the form. It's also been asked and answered.

A. So after the fact, after it's been paid, is that what you're asking me, like what would we do after the fact?

Q. Or even before the fact. If a claim -- if an individual went to a pharmacy and tried to fill a prescription.

A. So we won't fill it if it's not medically necessary. So if it doesn't meet our standards, then it actually won't fill at the point of sale.

Q. And what about if you became aware after the fact, what would be done?

MR. PENDELL: Objection.

MR. SCHNIEDERS: Same objections.

MS. LINN: Objection. Asked and answered. This was discussed at Dr. Wharton's deposition in November.

MR. PENDELL: And I'll say outside the scope then, too.

MR. SCHNIEDERS: Same.

MS. O'GORMAN: Are you instructing her not to answer?

MS. LINN: You can go ahead if you

know, but Dr. Wharton has covered this area and this wouldn't be in your capacity as ODM's rep.

A. I did just describe all these processes related to a data feedback group and trying to make sure that it doesn't happen again. And, as you know, this has been a concerted effort over the last several years that has resulted in a 40 percent drop in prescriptions as well as the development of newer modalities, like acupuncture, to try to deal with pain in ways that actually might be safer. There's also been a focus on predictive analytics so that we could have patients that were worried about being care managed in a proactive way and possibly participate in the program as I just described.

Q. Does ODM expect that doctors providing care to its covered patients will rely on clinical judgment as to what prescriptions to write?

A. Yes. We expect that clinicians do rely on clinical judgment, data, input from patients, other healthcare experts for their prescribing, yes.

Q. Would you expect them to make a

risk/benefit determination as to the risks and benefits of the prescription they're considering for that particular patient?

A. Yes.

Q. You testified a little bit about P&T committees. Do you recall that testimony?

A. (Witness nodding head affirmatively).

Q. Are P&T committees made up of medical professionals?

MS. LINN: Objection. This is outside the scope. Dr. Wharton answered this at his November deposition. So she's not going to cover that.

MR. PENDELL: Same objections.

MS. O'GORMAN: You won't let her answer that question?

MS. LINN: It's in the transcript of Donald Wharton's testimony from November of last year, so no, because that was ODM's official response of what a P&T committee is.

MR. DOVE: Just for the record, Dr. Wharton's testimony was limited to the time period that he was -- has been employed at Ohio Medicaid, so to the extent there are differences

from 2010 to '13, this witness is ODM's representative for all things that happened during that time period.

MS. LINN: You can answer in that limited scope.

A. So the membership of P&T is also coded in law. We do have clinicians, pharmacists and a variety of subject matter expertise that's actually part of that group.

Q. And what information is available to P&T committee members at the time they're considering whether a drug should or should not be put on a preferred drug list or formulary?

MR. SCHNIEDERS: Object to the form.

MS. LINN: Objection.

You can answer.

A. So oftentimes members bring their own information, often from clinical studies. Certainly all the FDA indications. So any existing information is actually what's discussed that goes into the recommendation of the P&T committee.

Q. Does that include the product label for the drug under consideration?

MR. SCHNIEDERS: Object to form.

A. Since I don't attend those meetings, I can't necessarily give you that level of specificity.

Q. Okay. But you can say that the P&T committee members certainly do their own research and bring that with them to the meeting?

MR. SCHNIEDERS: Object to form.

A. Yes, they do.

Q. Are you aware whether drug manufacturers are present at these meetings?

A. I'm actually not aware.

MS. O'GORMAN: I don't have any further questions. Thank you.

THE VIDEOGRAPHER: Off the record, 12:45.

(Short recess had.)

THE VIDEOGRAPHER: We're back on the record, 12:47.

EXAMINATION OF MARY APPLEGATE, M.D.

BY MR. SCHNIEDERS:

Q. All right, Doctor. My name is Chris Schnieders. We met briefly off the record. You know that I represent Cuyahoga County and the Plaintiffs in this matter, right?

A. Yes.

Q. Okay. I just have a few follow-ups that I want to ask you. If there's anything I ask you that you don't understand, please ask me to rephrase. I'll make sure I get it right so you can actually answer the question.

A. Thank you.

Q. Briefly, there were a few exhibits, like Exhibit 33, that were put in front of you. I don't know if you want to dig through the pile.

A. This is fine. I recall it, yes.

Q. You recall this?

A. Yes.

Q. And you recall that there were some aspects of it you were asked about regarding potential risk factors?

A. Yes.

Q. Things along those lines.

There's also other initiatives that ODB has taken along with partners in order to try to stem the effects of the opioid epidemic, correct?

A. Yes.

Q. This particular process that's in

place in Exhibit 33, is that funded by industry, by the manufacturers or the distributors or the pharmacies, related to opioids?

MR. DOVE: Objection to form.

A. No.

Q. That's something that you've taken on yourself, right?

A. Yes.

Q. If industry decided to figure out what the risk factors were and fund something like that, you would be interested in that, right?

A. Yes.

Q. If that had been done in 2011, you would have been interested in it, right?

MS. O'GORMAN: Objection.

A. Yes. Our quality improvement work has existed since I've been there.

Q. But industry has never come to ODB with that type of information, have they?

A. No.

MR. DOVE: You referred to ODB?

A. ODM I'm presuming?

Q. I'm sorry. ODM. I apologize for that.

So with regard to what industry has done, they haven't come to ODM with that type of information, correct?

A. Correct.

Q. And had they come to ODM with that type of information, you would have paid attention to it, right?

MS. O'GORMAN: Objection.

A. Yes.

Q. You can set that to the side.

Earlier and throughout this deposition you've been asked by counsel things related to the PDL. Do you recall that?

A. Yes.

Q. Okay. And what is the PDL?

A. The PDL is the preferred drug list.

Q. What does it mean to be preferred?

A. Okay. So let me restate this again. What gets on the formulary is what's FDA approved, and what gets on the preferred drug list is largely the result of the decision from the P&T committee. The term "preferred" is not a layperson term "preferred," so it doesn't mean that we're saying that that's what everybody needs to take. What it does suggest, there is a

correlation between what has a prior authorization requirement and what doesn't, but that's actually not absolute, as we mentioned with the consensus list. So, generally, 80 percent of the time if a drug is on the preferred drug list, it does not require a prior authorization, and if it's not preferred, then it does, but the medication may still be available.

Q. So things that are not on the preferred list may still be available, correct?

A. Yes.

Q. And there's a whole host of reasons why a drug might end up on the preferred list; is that fair?

A. That's correct.

Q. I want to take you back to some exhibits that you were shown in your first part of your deposition back in January. First is Exhibit 10. So let me dig through this pile and find it for you.

Exhibit 10, that's a P&T committee meeting minutes memorandum that you have in front of you; is that right?

A. Yes.

Q. And with counsel you were just discussing the P&T committee; is that right?

A. Yes.

Q. She asked you if you were aware if pharmaceutical manufacturers appeared at those meetings.

Do you recall that?

A. Yes.

Q. Do you see there in the third line where it says, "Approximately 25 stakeholders were present, most representing pharmaceutical manufacturers"?

A. Yes.

Q. So you're aware that pharmaceutical manufacturers actually do attend these meetings, right?

MS. O'GORMAN: Objection.

A. So these are -- none of our meetings in the department actually are secret, so these are public meetings, and often what happens is the committee members are actually part of the core group, but there could be a hundred people in the room, and stakeholders, patients, families, and here there is this note that there were mostly pharmaceutical manufacturers. So

yes.

Q. And it could be anybody that shows up, but in this particular note, it's mostly pharmaceutical manufacturers that come to those meetings, right?

A. So, again, I don't attend them so I don't know about all of the meetings. Certainly these minutes reflect that there were lots of pharmaceutical manufacturers, yes.

Q. You can set that one to the side.

I'm going to show you Exhibit 7 now. Here's a copy of Exhibit 7. Exhibit 7 is, again, another memorandum of the P&T committee minutes; is that correct?

A. Yes.

Q. If you look here, it says under the second portion where it starts with Stephanie Levine, RPH -- do you see that?

A. Yes.

Q. The second sentence says, "Approximately 50 stakeholders were present, most representing pharmaceutical manufacturers and advocacy associations."

Do you see where I've read that from?

A. Yes, I see that.
Q. Again, this is a public meeting and anyone can come, right?
A. Yes.
Q. But these minutes that were put in front of you during the first portion of your deposition reflect that approximately 50 stakeholders from pharmaceutical manufacturers and advocacy associations came?
A. Yes.
Q. Let's look at Exhibit 9. So Exhibit 9, this is, again, another P&T committee meeting minutes exhibit; is that correct?
A. Yes.
Q. And this one actually is the third paragraph. It says approximately 90 stakeholders were present at this one, right?
A. Yes.
Q. Most representing pharmaceutical manufacturers and advocacy associations. Have I read that correct?
A. Yes.
Q. So, again, open meeting, correct?
A. Yes.
Q. And it appears that 90 stakeholders

were there and most were representing pharmaceutical manufacturers and advocacy associations, right?

MS. McNAMARA: Objection.

A. That's correct.

MR. SCHNIEDERS: What's the objection, counsel?

MS. McNAMARA: She wasn't at the meeting. You're asking her to speculate.

MR. SCHNIEDERS: Well, this is from 2011 and she's the 30(b)(6) witness.

MS. McNAMARA: I'm pretty sure you made the same objections to our questioning, so --

MR. SCHNIEDERS: I just wanted to make sure I had a basis if I needed to cure it. Thank you.

Q. Let's look at Exhibit 17. Exhibit 17, this is from the Drug Utilization Review Board; is that correct?

A. Yes, it is.

Q. And is this also a public meeting that the outside is able to attend?

A. Yes.

Q. If you look at the bottom of the

paragraph that starts with, "Also present," the last sentence says, "Approximately 13 observers were present, most representing pharmaceutical manufacturers."

Do you see that?

A. Let me find it.

Q. Sure.

A. Yes, I see that.

Q. So you would agree that during your time at the Medicaid entity that it's been a constant that pharmaceutical industry has been represented at open meetings, correct?

MS. O'GORMAN: Objection.

MS. LINN: You can answer.

A. That is what the minutes reflect, yes.

Q. Let's go back to Exhibit 10 now that we've looked at those. Exhibit 10 are the meeting minutes that are dated October 7th of 2009, and this was put in front of you as part of the first part of your deposition. I want to ask you a question about something that appears at the bottom of the front page and continues on to the second page.

Under Subsection 2 at the bottom do

you see it says, "Drugs under consideration"?

A. Yes.

Q. And under that, under Subsection B, it's analgesics.

Do you see that?

A. Yes.

Q. If you go down to the last sentence that's on this page, it says, "Dr. Wilker also asked about addiction potential because the drug is C2, and according to the clinical presentation, has fewer side effects than traditional opioids."

Do you see that?

A. Yes.

Q. Do you see that based on the context of this paragraph, they're talking about an opioid called Nucynta?

A. Yes.

Q. If you go on to the second page there, you'll see it says, "The manufacturer's representative said there is potential for addiction but Nucynta has less opioid activity than traditional opioids."

Do you see where I've read that from?

A. I do.
Q. So in this instance we've got a manufacturer that has a representative there that is commenting on the safety profile of its drug, Nucynta, fair?
A. Yes.
Q. And this manufacturer's representative is saying that while there's potential for addiction, that Nucynta has less opioid activity than traditional opioids; is that fair?
A. That is what this states.
Q. And based upon that, it's leaving the conclusion that it's a safer alternative than other opioids?
MR. DOVE: Objection to form.
MS. LINN: You can --
A. That is what's indicated in this paragraph.
Q. If you wouldn't mind going to Exhibit 9 now. Exhibit 9 is a later meeting, it's approximately two years later, June 29th of 2011.
Do you see that?
A. Yes.

Q. And if you go to the second page, 2 of 6, under "Analgesic Agents Opioids" -- do you see that heading?

A. Yes.

Q. You'll see here two years later Dr. Hunter said he is in favor of Nucynta based on the potential for less diversion. The committee voted 7 to 1 in favor of the preferred status for Nucynta.

Do you see that?

A. I do.

Q. So here two years prior to this you see a manufacturer representative for Nucynta, which would be Ortho Janssen McNeil, lobbying on behalf of Nucynta, correct?

MS. O'GORMAN: Objection.

MS. LINN: You can answer.

A. Yes, it appears so.

Q. And two years later there's a placement of Nucynta on the preferred drug list; is that fair?

A. Yes.

Q. You can set that to the side.

I'm going to put in front of you what I'm marking as Exhibit 34, which is the

label that was in place at the time for Nucynta of the 2009 meeting. You'll see that on the front page of Exhibit 34, on the bottom right-hand side, it says, "Revised 03/2009."

- - - - -

(Thereupon, Applegate Deposition Exhibit 34, Nucynta Label, was marked for purposes of identification.)

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Q. Do you see that?

A. Yes.

Q. And you recall that when we looked at Exhibit 10, that that meeting was October 7th of 2009, correct?

A. Correct.

Q. So it appears that this would be the label that was in place at the time of that meeting, fair?

A. Yes.

Q. And if you go to page 5 of this, you'll see that there's a section that says, "Misuse and Abuse."

Do you see that?

A. I do.

Q. And here it says that Tapentadol, which is the generic name for Nucynta, that Tapentadol is a new opioid agonist and is a Schedule 2 controlled substance. Such drugs are sought by drug abusers and people with addiction disorders. Diversion of Schedule 2 products is an act subject to criminal penalty.

Do you see that?

A. Yes.

Q. Further, it says, "Nucynta can be abused in a manner similar to other opioid agonists, illegal or illicit."

Do you see that?

A. Yes.

Q. It doesn't say anything about this being a different kind of opioid that's not subject to abuse, does it?

A. It does not.

Q. Going further into the label, on page 12, under Subsection 9, at the very bottom, it again repeats a similar sentence, "Nucynta contains Tapentadol, a new opioid agonist, and is a Schedule 2 controlled substance," and it says, "Nucynta has an abuse potential similar to hydromorphone, can be abused and is subject to

criminal diversion."

Do you see that?

A. I do.

Q. Are you familiar with what hydromorphone is?

A. Yes.

Q. And is that Dilaudid?

A. Yes.

Q. Dilaudid is a substance that everyone is aware now can be abused, correct?

A. Yes.

Q. But here you've got a manufacturer telling you that the abuse potential for this particular drug was less, correct?

MS. O'GORMAN: Objection.

MR. DOVE: Object to the form.

A. That's correct.

Q. And they were coming to the meetings in an attempt to be placed on a preferred formulary, fair?

MS. O'GORMAN: Objection.

MR. DOVE: Object to the form.

A. That's correct.

Q. And these are the same manufacturers and industry components that are not funding

things like what we saw in Exhibit 33, correct?

MS. O'GORMAN: Objection.

MR. DOVE: Objection to form. No foundation.

A. That is correct.

Q. Lastly, I'm going to mark Exhibit 35.

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(Thereupon, Deposition Exhibit 35, Presentation Slides - OPQC MOMS+ Project, Regional Meeting - Northeast Ohio, Ohio Perinatal Quality Collaborative, May 22, 2018, was marked for purposes of identification.)

- - - - -

Q. Are you familiar with Exhibit 35?

A. Yes, I am.

Q. This is actually a presentation that you were a part of giving; is that right?

A. That's correct.

Q. What was the contact for this presentation?

A. We have gathered a partnership called the Ohio Perinatal Quality Collaborative,

and we have a number of efforts underway, two of which deal specifically with opioid use disorder.

One is focused on pregnant mothers with opioid use disorder and trying to coordinate care, provide access to medication-assisted treatment and psychosocial services, earlier identification, retention in care, things that actually lead to better long-term outcomes.

The second component is related to neonatal abstinence syndrome or caring for infants who had in-uterine exposure to opioids, so that we can do a better job ensuring that those babies have better neurocognitive outcomes.

MR. DOVE: Counsel, just for the record, this doesn't bear a Bates label? Was this something you printed off a website or was this part of a production.

MR. SCHNIEDERS: No. This is publicly available. It's from a website.

Q. Doctor, if I understood you correctly, it sounds like one part of this is a project that's trying to help those that are

dependent upon opioids; is that fair?

A. Yes.

Q. And another part is trying to help those infants that are born to mothers that are born at a time when they are also addicted to opioids; is that fair?

A. Officially the infant can't be addicted because they don't have the behaviors to seeking the next dose, so officially they're exposed to opioids before birth.

Q. Okay. And as part of that exposure, they have a whole list of sequelae that exist?

A. Yes. The constellation of symptoms we call neonatal abstinence syndrome.

Q. Can you tell us what the symptoms are for neonatal abstinence syndrome?

A. Yes. So these infants often are jittery, have tremors, can have seizure. They won't eat. They have diarrhea. They're very, very difficult to console and they're really irritable. So one of the most important things babies can do is they need to eat to maintain weight, and this is actually difficult for these babies.

Q. And while you said that they are

exposed, not addicted, these are things that are occurring, in part at least, due to the fact that their exposure has given them some of the same symptoms that someone that might be in withdrawal would incur, correct?

A. Yes.

Q. If we go into your presentation here, I want to ask about a few specific slides. They're not numbered so I'll do my best. They're back to back.

The third page here has a welcome from you that I think you would have offered to this group; is that fair?

A. Yes.

Q. Going further in, there's a whole host of other medical professionals that are involved in this particular presentation project, fair?

A. Yes.

Q. Going all the way to the page that looks like a green and blue map --

A. Yes.

Q. -- there's a slide that says, "Age-adjusted drug overdose death rates, by state, United States, 2016"?

A. Yes.

Q. And this has every state in the United States coded by a color; green meaning statistically lower than the U.S. rate, lighter blue meaning statistically the same as the U.S. rate, and dark blue meaning statistically higher than the U.S. rate; is that right?

A. That is correct.

Q. And so the states that are in dark blue would be the states that have drug overdose death rates that are higher than the typical in the United States; is that fair?

A. That is correct.

Q. And Ohio is one of those states, right?

A. Yes, it is.

Q. If you can move on to the page that is titled "Incidence of Maternal Opiate Use and NAS since 2004."

A. Yes.

Q. There's a chart here, and could you explain to me what this chart is?

A. This indicates a trend over time of the incidence of pregnant mothers using opioids, and they add NAS in here as well. So let me

think about this. This is actually -- this is actually the infant, not the mother. It's the incidence of neonatal abstinence syndrome from commercial -- mothers covered by commercial industries versus Medicaid.

Q. So this is talking about those little babies that we discussed that are born with this syndrome, right?

A. Yes.

Q. And if you look at the chart, I believe it has Medicaid, it has private insurance and all payers on that; is that right?

A. Yes.

Q. And the highest numbers on this chart are Medicaid, right?

A. That is correct.

Q. Is it fair to say that those on Medicaid, the babies born to women that are on Medicaid, have a disproportionately higher chance of having NAS?

MS. O'GORMAN: Objection.

A. Let me have you state that again.

Q. Sure. It wasn't a very good question.

Based on this chart here, I see the

Medicaid line is higher than the other two; is that fair?

A. That is correct.

Q. So the incidence of children born and covered by Medicaid that have NAS is higher than that which are born and covered by private insurance, fair?

A. That's correct.

Q. Do you have any understanding as to why that would be?

A. Yes. This actually gets into the question as to how it is you can become eligible for Medicaid. If you're in the hospital as a baby for over a month, you're eligible for Medicaid, and many of these babies have to stay in the hospital for weeks. So if they had -- they may become eligible just by virtue of such an extensive hospital stay.

The other thing that we are aware of is related to the nature of opioid use disorder. So let's say you develop this problem. You may be late for work. You may then lose your job. You then can't pay your car payment so now you have no transportation so you can't get another job, can't pay your rent, and all of a sudden

you're poor enough to meet the financial ability to be on Medicaid. So if the mother is on Medicaid, then the infant is eligible as well. So there are a couple of reasons that we -- those are two of the really big reasons it's not surprising to us that we see a disproportionate share of NAS infants being paid for by the Medicaid program.

Q. I think earlier you referenced the line "Journey to addiction through prescriptions." Do you recall that line?

A. Yes.

Q. And this would be consistent with that where you're seeing some people that might be caught in that spiral that ultimately do end up on Medicaid that maybe didn't start there, fair?

MR. DOVE: Objection to form.

MS. McNAMARA: Objection.

A. Yes.

Q. If we go on to the next slide, you'll see that there is a slide that's entitled, "NAS Statewide Rate Per 1,000 Live Births."

Do you see that?

A. Yes.

Q. And can you tell me what this chart is reflecting?

A. This is information from the Hospital Associations related to the number of infants who are discharged with a diagnosis of neonatal abstinence syndrome and it's calculated into a rate per thousand births. So that way we get consistency in how we measure this over a period of time. And what it shows is -- let's pick a year, 2007. For every thousand deliveries, only 2.5, so a little over two babies, actually had NAS, compared to the last date on this particular graph is 2015, in which case there were 16 babies. So that's an eight-fold -- approximate eight-fold difference over the period of those years.

Q. Fair to say that as you chart this over time, it's clear that there is a trend and it's spiking at its highest rate here in 2015, which is the last date you have data for on this chart, correct?

A. Yes.

Q. Go to the next page. There's a map of Ohio that says, "Discharge Rates for Neonatal

Abstinence Syndrome per 1,000 Live Births."

Do you see that?

A. Yes.

Q. And up in the corner here where Cuyahoga County is it says 1.9. What does that mean?

A. That actually means relative to the graph we just saw, for Cuyahoga County it was 1.9 babies had NAS out of every thousand live births.

Q. And this is for the five-year weighted average from 2004 to 2008?

A. Yes. So we do calculations over a period of years, so that if the numbers are really small, no one individual person could be identified for privacy reasons.

Q. The next slide has weighted average from 2005 to 2009; is that right?

A. Yes.

Q. And the number for Cuyahoga County has gone up to 2.4; is that right?

A. That is correct.

Q. The next slide has a date, a five-year weighted average from 2006 to 2010, correct?

A. Yes.
Q. And Cuyahoga County has changed colors at this point; is that correct?
A. It is, yes.
Q. Why is that?
A. The graphs are color coded into quintiles so that we can tell sort of how fast you're either getting better or getting worse so there's a visual of which parts of the state may be increasingly or decreasingly affected.
Q. And in this instance the color and number are both getting worse, right?
A. Yes. If you put these all side by side, I think you'll be able to see the trend just visually in the spreading geographic area as well as the severity of the problem across the state.
Q. If you go to the next slide, which is the five-year weighted average from 2007 to 2011, again you have another increase in Cuyahoga County; is that right?
A. Yes. It's 3.3.
Q. Going to the next slide, the weighted average from 2008 to 2012, again you have another number jump in Cuyahoga County?

A. Yes.
Q. It's up to 3.8 by that point?
A. Yes.
Q. Going to the next slide, the weighted average from 2009 to 2013, Cuyahoga County has jumped up to 4.5, correct?
A. That is correct.
Q. And the next slide, the weighted average from 2011 to 2015, Cuyahoga County has changed colors again; is that right?
A. Yes.
Q. And what does this color reflect?
A. This is actually in the top or the second to the top quintile, because the rate in that county is now 6.1 per thousand live births.
Q. So the trend continues to be a bad one, right?
A. That's correct.
Q. If you go to the next slide, you've got something here that's titled "What a Difference Over the Past Seven Years," and it gives a map on the left-hand side from '04 to '08 weighted average and on the right-hand side from 2011 to 2015; is that right?
A. That's correct.

Q. And you can see the difference in colors and in numbers in the majority of these counties, right?

A. That is correct.

Q. In 2004 to 2008 it appears that there were only three counties that were in the brown; is that right?

A. That's correct.

Q. And then over on the right-hand side, it appears that a majority of the counties in the state are in the dark brown at that point; is that right?

A. Yes. So on the left -- let's just clarify -- it's not the darkest color brown, it's the second to the darkest, whereas in the most recent one, 2011 to 2015, we do see a predominance of the worst rate bracket.

Q. And that's fair. So on the left-hand side there's only three of the four categories that are even showing up and the worst of the colors is not one of them, right?

A. That's correct.

Q. Whereas over on the right, the worst of the colors is the majority of the state?

A. That's correct.

Q. If we go to the next page that's titled "MOMS, Maternal Opiate Medical Support" --

A. Yes.

Q. -- could you explain to us what the MOMS project is?

A. Yes.

So we appreciated that mothers who had this problem with opioid use disorder had great difficulty getting care. They either received obstetrical care, where we were trying to make sure the baby was growing properly because the mother was pregnant, or they got care for their opioid use disorder, but often not both together at the same time.

So historically these services were funded separately, not just at the state level but also at the federal level, and there's different language, there's a different culture, there are different eligibility requirements, and trying to connect the two was actually quite difficult. So even if women were trying to seek treatment, they had difficulty adhering to what the best evidence-based practice was.

So we gathered kind of a core team

from both the behavioral health treatment side as well as the obstetrical side to try to explain what ideal care looked like on both sides, to try to figure out could we create a system that actually takes care of the women without the women having to glue these pieces together in order to get to a better outcome. And so the MOMS project was all about the details of what kind of support they needed and what we asked the health systems and clinicians to do to do a better job to take care of them.

Q. And over the last several years, programs like the MOMS program and other initiatives that have been put forward by the Medicaid entity and the state and the counties, they've helped somewhat with regard to the opioid epidemic; is that fair?

A. We have done a better job with treatment, yes.

Q. But it's not a quick fix, is it?

A. No.

Q. And the fix for the opioid epidemic is still something that's going to take a lot of work and a lot of time?

A. Yes.

So when you say "fix," there are a couple of things. We still have to deal with people who currently have the problem, because just because the mother is pregnant now doesn't mean she won't be again in the future. So there are future babies potentially still at risk. And at the same time you're trying to deal with the existing problem, you need to prevent new ones from starting. So it actually is a pretty complex effort across multiple parts of the health system.

MR. SCHNIEDERS: Thank you, Doctor. I appreciate your time here today.

THE VIDEOGRAPHER: Off the record, 1:21.

(Recess had.)

THE VIDEOGRAPHER: We're back on the record, 1:34.

FURTHER EXAMINATION OF MARY APPLEGATE, M.D.

BY MS. O'GORMAN:

Q. Good afternoon again. I just have a few more questions for you.

You were asked by counsel for Plaintiff about various initiatives undertaken by the ODM and whether industry participants had

provided support.

Do you recall those questions?

A. Yes.

Q. Have you ever been in contact with manufacturers of pharmaceutical drugs or other industry participants to request support for opioid-related initiatives?

A. We're actually not allowed to do that. That would represent a conflict of interest.

Q. So would it be a conflict of interest for the manufacturers to have provided support or simply for you to contact them?

A. So I'm not the lawyer. I can just tell you that we have strict standards around conflicts of interest, so even the appearance of impropriety would be problematic for us.

Q. Okay. So if support were to be offered by manufacturers or other industry participants, you would not be able to accept that; is that correct?

MR. SCHNIEDERS: Object to the form.

MR. PENDELL: Objection.

A. So I'm not sure that that's actually true. I cannot go out and ask for that because

it would be the appearance of impropriety.
Q. If a manufacturer came to you and offered support, would you be able to take -- accept that offer?
A. I'd have to defer to legal folks. I'd have to defer to legal counsel.
Q. Do you recall being asked about some P&T committee meeting minutes?
A. Yes.
Q. Now -- and some of those meeting minutes reflected that there were representatives of pharmaceutical manufacturers in attendance. Do you recall that?
A. Yes. Not as committee members but as stakeholders, yes.
Q. Was there a list of participants or attendees at these meetings retained as far as you know?
A. I'm not sure if they have people -- generally in these meetings people sign in. The documents that were given did not include the attendance sheet, so it was just a summary statement as to approximately how many were there at that time.
Q. Was the attendance sheet retained

and stored somewhere?

A. I did not attend so I actually don't know that level of detail.

Q. Okay. Does the fact that manufacturers' representatives may have been in attendance at a meeting mean they spoke at the meeting?

MR. SCHNIEDERS: Objection to form.

A. The minutes reflect that they did speak.

Q. If there were 30 manufacturer representatives in attendance but only, say, two or three were noted in the meeting minutes, does that mean that only those couple actually spoke?

MR. SCHNIEDERS: Objection to form.

A. I wasn't there so I actually can't comment on the nature of it. My understanding is that there's discussion, there's a more formal process now in which people who want to speak need to submit that request in advance, but back then I actually can't tell you what the process was.

Q. If somebody spoke at the meeting, would it be reflected in the minutes?

MR. SCHNIEDERS: Object to the form.

A. Yeah. I actually can't comment on the degree to which every detail was included in the minutes.

Q. And the P&T committee meetings included consideration of oral drugs, not just opioids, correct?

A. That's correct.

Q. So there would be pharmaceutical manufacturer representatives for various types of drugs other than opioids, correct?

A. I would presume so, yes.

Q. Okay. And you were asked specifically about a clinical presentation made by a manufacturer representative with regard to Nucynta in 2009.

Do you recall that?

A. Yes.

Q. Would you expect that the P&T committee would do its own investigation independent of whatever information they were given by the pharmaceutical representative?

MR. SCHNIEDERS: Object to the form.

MR. PENDELL: Objection.

A. The purpose of the P&T committee is actually to have expertise in all these fields

to provide input. Many of the members actually are researchers themselves. So I think all of the information is taken into consideration, but the agency does not conduct independent investigations of every drug on the formulary.

Q. Does the P&T committee conduct that independent investigation?

MR. SCHNIEDERS: Object to the form.

A. So I think there's review of the literature, but they do not conduct studies. So many of the members may be associated with institutions that are looking at a variety of topics but that's actually not the primary purpose of the P&T committee.

Q. Would you expect that a presentation by a pharmaceutical manufacturer would supplant the research and judgment of the medical professionals on the P&T committee?

MR. SCHNIEDERS: Object to the form.

A. I wouldn't say supplant. Perhaps complement. I'd imagine that this was some of the discussion that ensued at these meetings. I think clinicians have a different view perhaps than what the drug companies may have and it may or may not match their experience or their

concerns.

Q. And the members would -- of the committee would rely on their own clinical judgment and experiences and not what the manufacturer's representative told them; is that what you would expect?

MR. SCHNIEDERS: Object to the form.

A. I would expect that they actually do their own readings, have a good understanding of the medical literature, and, like I said, any additional information -- could be that those representatives had additional information that may have been helpful to the P&T committee.

MS. O'GORMAN: I have nothing further. Thank you.

EXAMINATION OF MARY APPLEGATE, M.D.

BY MR. PENDELL:

Q. I have one follow-up, Doctor.

Have you ever heard, in either your personal capacity or in your capacity as a representative of the ODM, of a single opioid manufacturer reaching out to the Ohio Medicaid, offering assistance to help with the opioid crisis? Have you ever heard of that happening?

A. That has not happened. Actually, as

we tried to be strategic about how we were going to address this issue at one of the earlier task forces, we reviewed every public health promising practice. We looked at collective impact. We had every agency, every stakeholder that we could think of who actively participated, and the only one in that box which I think was submitted at one of the earlier, like prior to my first testimony -- the only intervention that has not happened is the one in which the pharmaceutical industry contributed to the solution.

MR. PENDELL: I appreciate it. I have no further questions, Doctor.

MS. ZINSMASTER: If we have 30 seconds or so left, I have one clean-up question from the pharmacy perspective.

MR. PENDELL: I don't have any objections.

THE VIDEOGRAPHER: Off the record, 1:41.

(Short recess had.)

THE VIDEOGRAPHER: We're back on the record, 1:42.

EXAMINATION OF MARY APPLEGATE, M.D.

BY MS. ZINSMASTER:

Q. Dr. Applegate, I'm Kristin Zinsmaster. I represent Walmart and I have just one question for you, but it takes us back in time a little bit so I'll set the stage.

Ms. Han was asking you about death investigations and you testified that the Department of Health performed such investigations to your knowledge, correct?

A. Well, officially they house vital statistics so they have the death certificates, which are filled out by the coroners, who are the ones who actually do the investigations and the determination of causes of death.

Q. Okay. So coroners determine cause of death and the Department of Health houses the data or the results of that investigation?

A. That's correct.

Q. Thank you.

And you testified earlier that you were not aware of either a coroner or the Department of Health investigating manufacturers or distributors, correct?

A. Correct.

MR. PENDELL: Form.

Q. Is your answer the same when it comes to pharmacies? Are you aware of any investigation that involved a pharmacy?

A. Well, at least within our agency, there is a fraud and abuse section, and so if there are unusual patterns by either providers, clinicians or by pharmacies, there's actually an investigation. And in my earlier testimony I did talk about one of the first steps that we took was actually to close what they called pill mills, which were either clinical practices or associations of pharmacies with clinical practices or even pharmacies that actually were not following the laws as it relates to prescribing.

Q. So pill mills are prescribers, correct?

MR. SCHNIEDERS: Object to the form.

A. Yes, but some -- some clinics actually may have a pharmacy within them.

Q. Meaning that the prescriber dispenses the medication in addition to prescribing it, correct?

A. Or there may be a pharmacy within it or there may be a very tight pharmacy associated

with it so that every client goes to the same pharmacy. So there are a number of different arrangements when those pill mills were closed.

Q. Okay. But are you aware -- taking us back to the specific question, are you aware of any death investigation that involved a pharmacy?

MR. SCHNIEDERS: Object to form.

MR. PENDELL: Objection.

A. So I personally can't answer that because it may be the Board of Pharmacy or a different state department that actually looked into that.

Q. But you personally are not aware of such an investigation?

A. No.

MS. ZINSMASTER: That's it for me. Thank you, Doctor.

THE WITNESS: Thank you.

MR. DOVE: Counsel, I just want to say a couple things for the record.

First, as we said early in the deposition, it's our position that the deposition of Ohio Medicaid remains open. We're still waiting on documents, e-mails from

Dr. Wharton and from Dr. Applegate, and some additional documents, and so we're going to work with the department to figure out the best way to deal with that, but in our view, we are entitled to additional testimony.

And, in addition, there were certain areas of testimony today where Dr. Applegate conceded that she was not the person most knowledgeable about that area and that she would have to defer to her pharmacy team. So, again, these are areas we can negotiate and discuss, but our position is the deposition remains open.

MR. PENDELL: It is our position that -- first of all, we'll object.

It is my understanding from counsel for the witness that she offered to move the deposition date so that you could have those documents and you refused to do so. You've now sat with this witness on two occasions. There was another witness that you sat with. So that's now three witnesses that you've had on these topics. You gave broad deposition topics on top of it. She's not obligated as a corporate witness to be able to anticipate every single question that you're going to ask. And I

would also note for the record that several times at least today and in the transcript I read from last time you would put a document in front of her, read it and then ask her isn't that true. So I think that you've more than had ample opportunity. You may not have chosen to use the time the way that in retrospect you wish you had, but we do object to keeping the deposition open.

MS. LINN: And I would just also add that we've made our pharmacy team names known from months and months ago, that those were an option to have as a representative and as a witness, so that's not been a secret either.

MR. DOVE: I would just have to say for the record, from our perspective, Michelle Barger's name was identified early on and then the department decided to pull her. She did not want to be deposed. And so we've been trying to work cooperatively with the department in its selection of witnesses. If you're saying those witnesses are available for deposition, that's something we can take into consideration as to who is the appropriate person for the next round. It's just -- you know, again, we don't

have to get into --

MR. PENDELL: I will object that discovery is closed as far as I know. It's been closed for like a month.

MR. SCHNIEDERS: And these are not new topics at this point. You served an incredibly broad 30(b)(6). This witness was adequately and above adequately prepared to answer questions related to that 30(b)(6) that were within the scope. So we would object.

MS. ZINSMASTER: Plaintiffs' counsel, you requested yourself to keep this deposition open. Are you withdrawing that request?

MR. SCHNIEDERS: To be clear, I didn't say -- I said we might ask, based upon the production we received at 6:00 last night, when we have a chance to look at those, if we need to. As of right now, we are not holding this deposition open.

MS. ZINSMASTER: I wanted to clarify the status of that request.

MR. PENDELL: We will withdraw.

MR. DOVE: Thank you.

THE VIDEOGRAPHER: Off the record,

1:49.

(Deposition concluded at 1:49 p.m.)

- - - - -

Whereupon, counsel was requested to give instruction regarding the witness' review of the transcript pursuant to the Civil Rules.

SIGNATURE:

Transcript review was requested pursuant to the applicable Rules of Civil Procedure.

TRANSCRIPT DELIVERY:

Counsel was requested to give instruction regarding delivery date of transcript.

REPORTER'S CERTIFICATE

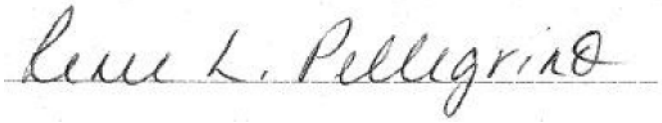
The State of Ohio,)
) SS:
County of Cuyahoga.)

I, Renee L. Pellegrino, a Notary Public within and for the State of Ohio, duly commissioned and qualified, do hereby certify that the within named witness, MARY APPLEGATE, M.D., was by me first duly sworn to testify the truth, the whole truth and nothing but the truth in the cause aforesaid; that the testimony then given by the above referenced witness was by me reduced to stenotypy in the presence of said witness; afterwards transcribed, and that the foregoing is a true and correct transcription of the testimony so given by the above referenced witness.

I do further certify that this deposition was taken at the time and place in the foregoing caption specified and was completed without adjournment.

I do further certify that I am not a relative, counsel or attorney for either party, or otherwise interested in the event of this action.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my seal of office at Cleveland, Ohio, on this 2nd day of April, 2019.



Renee L. Pellegrino, Notary Public
within and for the State of Ohio

My commission expires October 12, 2020.

Veritext Legal Solutions
1100 Superior Ave
Suite 1820
Cleveland, Ohio 44114
Phone: 216-523-1313

April 2, 2019

To: Morgan Linn, Esq.

Case Name: In Re: National Prescription Opiate Litigation

Veritext Reference Number: 3255027

Witness: Mary Applegate, M.D. Deposition Date: 3/28/2019

Dear Sir/Madam:

Enclosed please find a deposition transcript. Please have the witness review the transcript and note any changes or corrections on the included errata sheet, indicating the page, line number, change, and the reason for the change. Have the witness' signature notarized and forward the completed page(s) back to us at the Production address shown above, or email to production-midwest@veritext.com.

If the errata is not returned within thirty days of your receipt of this letter, the reading and signing will be deemed waived.

Sincerely,
Production Department

NO NOTARY REQUIRED IN CA

DEPOSITION REVIEW
CERTIFICATION OF WITNESS

ASSIGNMENT REFERENCE NO: 3255027
CASE NAME: In Re: National Prescription Opiate Litigation
DATE OF DEPOSITION: 3/28/2019
WITNESS' NAME: Mary Applegate, M.D.

In accordance with the Rules of Civil Procedure, I have read the entire transcript of my testimony or it has been read to me.

I have made no changes to the testimony as transcribed by the court reporter.

_____ _____
Date Mary Applegate, M.D.

Sworn to and subscribed before me, a Notary Public in and for the State and County, the referenced witness did personally appear and acknowledge that:

They have read the transcript;
They signed the foregoing Sworn Statement; and
Their execution of this Statement is of their free act and deed.

I have affixed my name and official seal

this _____ day of_____, 20____.

_____
Notary Public

_____
Commission Expiration Date

DEPOSITION REVIEW
CERTIFICATION OF WITNESS

ASSIGNMENT REFERENCE NO: 3255027
CASE NAME: In Re: National Prescription Opiate Litigation
DATE OF DEPOSITION: 3/28/2019
WITNESS' NAME: Mary Applegate, M.D.

In accordance with the Rules of Civil Procedure, I have read the entire transcript of my testimony or it has been read to me.

I have listed my changes on the attached Errata Sheet, listing page and line numbers as well as the reason(s) for the change(s).

I request that these changes be entered as part of the record of my testimony.

I have executed the Errata Sheet, as well as this Certificate, and request and authorize that both be appended to the transcript of my testimony and be incorporated therein.

_____ _____
Date Mary Applegate, M.D.

Sworn to and subscribed before me, a Notary Public in and for the State and County, the referenced witness did personally appear and acknowledge that:

They have read the transcript;
They have listed all of their corrections in the appended Errata Sheet;
They signed the foregoing Sworn Statement; and
Their execution of this Statement is of their free act and deed.

I have affixed my name and official seal this _____ day of_____, 20____.

_____
Notary Public

_____
Commission Expiration Date

ERRATA SHEET

VERITEXT LEGAL SOLUTIONS MIDWEST

ASSIGNMENT NO: 3/28/2019

PAGE/LINE(S) / CHANGE /REASON

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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